

ge-nome (n): All of the genetic information, all of the hereditary material possessed by an organism.
ad-vo-ca-cy (n): To influence public-policy and resource allocation decisions within political, economic, and social systems and institutions; it may be motivated from moral, ethical or faith principles.

Overview: A complete copy of the entire human genome is contained in each and every cell of your body. Your genome contributes to those similarities, which make you part of the human species, and to those differences, which distinguish you from your neighbor. It is a record of your health, your history, your ancestry, and your identity. The size of your genome is equivalent to 200 volumes of the 1000-page Manhattan telephone book - it would take you 9.5 years to read all 200 volumes and you would need 3 gigabytes to store it on a computer. Modern "next-generation" sequencing machines can read your entire genome in only a few short months, yet scientists don't yet know the meaning of all the "words." Like all genomic information, your genome will be uploaded to a public database so others can access it. Genome studies will result in important breakthroughs that will revolutionize science, medicine, and even, conservation. However, the study of genomes will also open the door to a netherworld of unintended legal and ethical consequences. How will we interpret all this genomic information? What will we do with it? What are the positive and negative impacts on society? What diseases or disorders are coded in your genome? Will you be denied insurance because of the genes you carry? Will your employer encourage you to seek employment elsewhere because your genome has the potential for significantly increasing company health care costs? Who owns your genome? What policies and laws are in place to protect the use of your genomic information? How will you protect your health, your history, your ancestry, and your identity? *As we progress into the genomics era, will we be prepared to address these impending crucial issues?*

Genomics is a "wicked problem", with important wide-ranging implications and great potential to simultaneously benefit and harm humanity. Among ethical, legal and societal issues in genomic technology is the use and misuse of genomic information. Privacy and security of personal information, both key concerns in the collection and management of health information, are intensified since inadvertent disclosure of genetic information not only violates the rights of the individual, but that of his/her family. Even when the information is de-identified, protection of such information through user education, information access and sharing policy, and procedural and technological schemes of security is of critical importance. With genomic advances, policymakers will need to act as partners/facilitators of basic research, setting clear standards for its responsible use, while articulating standards, evaluating processes to measure the relative risks and rewards, and establishing sanctions for those who violate policy.

To balance the good with the bad, academic institutions need to embrace these scientific advances, while leading society in the development of effective policy and ethical guidelines for their use. They must act as models for the responsible application of genomic technology. In short they must form interdisciplinary coalitions that, 1) place themselves at the forefront of discovery, 2) ensure the effective interdisciplinary training of students so they are prepared to enter the genomics era, 3) transform society through innovative educational experiences, and 4) pioneer integrative strategies that leverage the strengths and synergies among policy, business, and science. Through the offering of quality undergraduate and graduate degrees, strong focuses in the liberal arts and business, and a commitment to public education, Indiana State University (ISU) has established itself as a leading academic institution poised to advocate important societal issues. Now, *to further advance research, education, and community engagement at ISU, we propose the establishment of The Center for Genomic Advocacy (TCGA), whose mission is to develop a community of genomic advocates through interdisciplinary studies in biology, political science, business, ethics, and health. Genomic Advocacy promotes the responsible use of genomic technology for the betterment of society, while mitigating the negative effects that such technology may have on individuals.* Genomic advocacy brings an *interdisciplinary perspective* to addressing ethical

dilemmas, psychological and social issues associated with the disclosure of genomic information, and access to genomic information, testing and therapy. Policy implications for the misuse of genomic information, such as genetic discrimination and stigmatization, and the oversight and regulation of genomic testing services, are also areas requiring collaboration among researchers traditionally separated by disciplinary boundaries. Ethical principles, such as autonomy, veracity, beneficence, nonmaleficence, and justice, can help guide decision-making in the collection, storage, retrieval, and use of genomic information. TCGA unites these areas in a plan of insight, one in which faculty members can engage in novel interdisciplinary research, while simultaneously strengthening the academic programs at ISU in a modern, cutting-edge direction. *Genomic Advocacy will usher ISU into the genomics era.*

The goals of TCGA will be to, 1) foster an interdisciplinary academic environment through shared resources, meetings, seminars, and workshops, 2) establish new educational programs, including a certificate program in Genomic Advocacy and a professional masters degree in Genetic Counseling, 3) serve society through consultation, education, and the application and advancement of genomics, and 4) promote technological innovation and economic development. Highlights of TCGA include:

1) A *new interdisciplinary research focus*, beginning with Biology (Tuttle, Gonser, Stuart, Romanov), Political Science (Myers), and Philosophy (Barad), and the Scott College of Business (Chao, Mikolaj), and expanding to include other disciplines such as computer science, psychology (Shin), and sociology. Our collaboration extends to the College of Nursing, Health, & Human Services, who will assist in the administration of a Genetic Counseling program. TCGA will include academics and community engagement, and it will join 3 broad-based disciplinary areas (science, social science, and business) to bring an *interdisciplinary perspective* to ethical, psychological, and social issues associated with the increase of genomic information. We will integrate the community of Genomic Advocates by sponsoring informal meetings, which will serve to break down traditional barriers and help to promote interaction, an interdisciplinary journal club held once a month to present relevant research papers, and an annual TCGA symposium open to the University, neighboring academic institutions, and the public. The symposium will serve as an instructional tool, and a vehicle of outreach and recruitment. In addition, we will sponsor an annual TCGA speaker and present our research at professional meetings. To provide experiential learning in genomics, we will establish a genomics research facility with DNA analysis capabilities. This will be a hands-on facility designed to give students first-hand experience with modern genomic technologies. In consultation with the San Diego Zoo, the ISU genomics facility will include a Midwest "Frozen Zoo®" where genomic samples from endangered Indiana plants and animals (e.g. bats) will be archived for conservation (see http://www.sandiegozoo.org/conservation/science/at_the_zoo/the_frozen_zoo/).

2) *New educational programs* to broaden academic opportunities and increase enrollments.

a) *Certificate in Genomic Advocacy* - A working knowledge of genomics will benefit those interested in health- and conservation-related fields as they must learn to interpret genomic data and understand the societal issues arising from insurance, legal, and ethical issues. Similarly, students of political science, criminology, and business must interpret genomic information while understanding its limitations if they are to effectively establish policy. To instill an interdisciplinary understanding of genomics, *an educational goal of TCGA is the establishment of a certificate program in Genomic Advocacy.* We envision a 20-credit hour certificate including courses in biological genomics, genomics issues in business, genomics policy, and bioethics (12 credits), plus an integrating seminar (3 credits), and a 5-credit internship in which students educate and aid a community partner. The classes will be offered as 500-level distance courses so they are open to both undergraduate and graduate students, as well as non-traditional students who are already in the health and nursing, insurance, law, criminology, or the business workforce. Generated funds will be used to support TCGA initiatives.

b) *Masters in Genetic Counseling* - Genetic Counselors provide information and support to people at risk for genetic disorders. They identify families at risk, analyze inheritance patterns, counsel families on available health options, and serve as advocates for their patients (see http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genecounseling.shtml). Currently there are only 27 accredited genetic counseling programs in the US (American Board of Genetic Counseling, Inc.; <http://www.abgc.net/ABGC/AmericanBoardofGeneticCounselors.asp>), none of which serve the southern Indiana, southern Illinois, Kentucky, Tennessee, and Missouri areas. Therefore a second, *long-term educational goal of TCGA is the development of a professional masters degree in Genetic Counseling*. ISU is an ideal institution in which to establish a genetic counseling program as the foundation disciplines already reside within the College of Arts & Sciences (i.e. basic science, mathematics, counseling psychology, and sociology). In addition, ISU has a strong health focus with connections to the Rural Health Innovation Collaborative (<http://www.therhic.org/elements.html>) and the College of Nursing, Health, & Human Services (NHHS). To help ensure the success of a genetic counseling program, NHHS has agreed to, 1) provide clinical laboratory space within the Landsbaum Center for Health Education, 2) share in critical staff positions (e.g. administrative assistant, insurance administration) and training (e.g. health communication), and 3) assist in the establishment of clinical experiences and referral for those enrolled in the program.

3) TCGA will connect an *extensive network of external partners and stakeholders*, including current collaborators Dr. Wesley Warren (Genome Institute at Washington Univ), Dr. David Clayton (Institute for Genomic Biology, Univ of Illinois), Dr. Oliver Ryder (Institute for Conservation Research, San Diego Zoo), Dr. Scott Edwards (Dept of Organismic & Evolutionary Biology, Harvard Univ), Dr. John W. Bickham (Center for Environment, Purdue Univ), and Dr. Walter Messier (Chief Scientific Officer, Evolutionary Genomics LLC). TCGA will benefit neighboring colleges (SMWC, RHIT, DePauw Univ) that have no access to genomics resources. Purdue University has invited ISU to be a part of the *Indiana Genomics Consortium*, which fosters connections between all genomics institutes and researchers in the state. Finally, the establishment of TCGA will expose educators and non-scientists to the new discipline of genomic advocacy.

4) TCGA will *promote technological innovations and economic development*. The consultation and educational services provided by TCGA will have high entrepreneurial and commercial potential, and will contribute to the economic development of the community and state.

Rationale & Significance: As technology advances, it is imperative that ISU experience a parallel expansion in academics so that the changing needs of society are met. TCGA serves as a new model for a service-based interdisciplinary center that advances scholarship and educational opportunities, as well as serves the community through ethical counseling in business, policy, medical, and environmental issues. *TCGA aligns with the strategic plan by increasing enrollments and student success through new educational programs in Genomic Advocacy and Genetic Counseling, by diversifying revenue through tuition new, grants and contracts, and entrepreneurial opportunities, by enhancing experiential learning and community engagement, and by attracting, recruiting and retaining talented faculty and staff.*

1) *TCGA will foster new interdisciplinary avenues of research.* Through genomic advocacy, we will be in a prime position to garner additional funding through federal agencies, foundations, and business partners (e.g. Lilly, Pfizer, Monsanto).

2) *TCGA would place ISU in a prime position to contribute to the Life Science Initiative.* Indiana was identified as one of the country's top four life science leaders because it boasts one of the highest concentrations of bioscience jobs (Growing the Nation's Bioscience Sector: State Bioscience Initiatives 2006). As a result, Indiana has become a key area for the development of a Life Sciences Initiative, and the Indiana BioCrossroads network (<http://www.biocrossroads.com>) was formed to foster a positive feedback system that facilitates its growth. To ensure an adequate investment on returns, there is a desire for much of the workforce for the initiative to primarily come from within Indiana. ISU is in a prime position to contribute to this vital program and

Genomic Advocacy is the institution's instrument of delivery - its broad scope will provide the necessary training for technology-related industries and could lead to an ISU-affiliated business incubation facility (e.g. Rose-Hulman Ventures, Purdue Research Parks).

3) TCGA would benefit ISU students by providing them with a new avenue of training. A National Academy of Sciences report recommended that universities "broaden curricular options" and train students in a "breadth of academic and career skills" (Natl Acad Sci, 1995). TCGA proposes an interdisciplinary approach to addressing the "wicked problems" presented by genomics, one in which students will be well-prepared for the ever changing workplace.

- a) Genomic Advocates in health-related fields: Medical professionals, nurses, and pre-professional students will not only learn to correctly interpret genomic data but they will also gain an understanding of the societal implications of those data. Advocates with training in the areas of counseling, social work, or psychology may advise those struggling with knowledge gained from genomic testing.
- b) Genomic Advocates interested in environmental issues: Applying whole genome studies to conservation and agricultural issues will be key in developing comprehensive plans for species management, as well as determining safe practices for genetically modified organisms (i.e. GMOs). Advocates can educate and advise farmers and environmentalists.
- c) Genomic Advocates interested in policy, law, & forensics: Genomic advocacy will allow the government to ensure the safe and responsible use of genomic technology. Members of genomic advocacy groups would act as ombudsmen to answer the questions of those who have been affected or will potentially be affected by this technology. Advocates could provide assistance in judicial or quasi-judicial proceedings, and serve as advisors to the federal, state, and local governments, the private sector and other non-profit groups.
- d) Genomic Advocates in business: Business professionals and students with genomic advocacy certificates will aid in developing risk management and insurance policy (e.g. Genetic Information Nondiscrimination Act of 2008, <http://www.genome.gov/10002328>). With widespread adoption of information and communication technology (ICT) and the use of the Internet as a key information resource, advocates will determine consumer health needs and design and evaluate genomic information websites to empower consumers to take active roles in their health management.

Estimated Costs: The primary costs associated with this initiative are faculty hires (10 over 5 years) that are strategically chosen to effectively deliver the proposed curriculum, while contributing to the intellectual and research goals of TCGA (Tables 1 & 2).

Table 1. Proposed budget for TCGA.

Item	Description	Estimated Cost
Faculty Positions	Expertise needed to enhance TCGA and to administer the curriculum	\$ 750,000
Genomics Facility	Equipment for hands-on genomics education & research	\$ 180,000
	Graduate Student Stipends (3) - genomics facility & assist in courses	\$ 45,000
TOTAL		\$ 975,000

Table 2. Faculty hiring plan for TCGA.

Year	Position	Support Purpose
1-2	Bioethics	Study ethical questions that arise among biology, politics, law, & philosophy.
1-2	Law/Policy	Identify, analyze, & propose policy responses to genomic challenges.
1-2	Business	Study, develop, & commercialize genomic-driven solutions to address challenges.
1-2	Human Geneticist	Focus on genomic approaches to understanding the mechanisms of disease.
2-3	Bioinformatics	Uses computer science to manipulate & process complex genomic data.
2-3	Embryologist	Study of conception & growth changes that occur in the embryo.
2-3	Insurance	Risk management, insurance, & financial businesses associated with genomics.
3-5	Psychology	Focus on issues related to genomic disease & how it affects behavior.
3-5	Population Genetics	Study the genetic structure of populations and how it changes through time.
3-5	Cytogenetics	Research the molecular pathology of genetic diseases and disorders.

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Appendix 1: Plan for the \$4000 in exploratory funds: If TCGA is chosen to proceed to the next round, we will use the seed money to, 1) establish collaborative relationships, 2) review curricular structure, 3) examine modern genomic laboratories, and 4) investigate the administrative structure of the centers/institutes/programs listed below. We will send 2 faculty members to each destination. Five of the seven locations are within driving distance and should therefore require minimum funds (approximately \$300-600 per location).

1) The Center for Genetic Research Ethics and Law (<http://www.case.edu/med/bioethics/cgreal/>) at Case Western Reserve University.

"The Center for Genetic Research Ethics and Law (CGREAL) at Case Western Reserve University (CWRU) was established in 2004 with two missions: to conduct transdisciplinary research on ethical and policy issues in the design and conduct of human genetic research, and to recruit new scholars and trainees to work on these issues.

To date, CGREAL has explored a range of ethical issues in the design and conduct of genetic family studies, genetic epidemiology, and genomic variation research. In the next five years, we will follow the trajectory of genomics into its "translational" phase, where expanded research needs and higher clinical aspirations are creating new ethical, legal, and social challenges for genomic researchers and society."

2) The Institute for Genome Sciences & Policy (<http://www.genome.duke.edu/>) at Duke Univ.

"The Institute for Genome Sciences & Policy is Duke University's response to the **Genome Revolution**, with global, comprehensive approaches to the study of life. We - scientists and the public together - stand at a new threshold leading to deeper understanding and enhancement of the human experience. What distinguishes IGSP is its breadth and its purposeful focus on health and social policy. We bring together scientists, engineers, physicians, lawyers, policymakers, business leaders, economists, ethicists, humanists and students to explore the genome, embrace its potential and enrich the human condition."

3) BioCrossroads (<http://www.biocrossroads.com/>)

"The mission of BioCrossroads is to serve as a catalyst for the continued growth of Indiana's robust life sciences industry. By doing so, we will create an environment that provides more economic opportunity and a thriving entrepreneurial network as well as better healthcare for our communities and inspiration for young talent.

We implement our mission by providing money and support to life sciences businesses and launching new life sciences enterprises, expanding partnerships among Indiana's life science institutions, promoting science education and building awareness through the marketing of Indiana's life sciences industry."

4) The Center for Bioethics (<http://bioethics.iu.edu/>) at the Indiana Univ School of Medicine.

"The Center is recognized throughout the state and around the globe as a primary source for bioethics research and new information. Research addresses ethical, legal, and social issues in healthcare and science with an emphasis on multidisciplinary approaches. Topics range from genetics to organ transplantation, medical research to health privacy, informed consent to pandemic flu preparedness."

5) The Department of Medical & Molecular Genetics, Indiana University School of Medicine (<http://genetics.medicine.iu.edu/education/master-of-science-genetic-counseling-program/>).

"The Department offers a Masters of Science in Genetic Counseling, which is fully accredited by the American Board of Genetic Counseling."

6) The Genome Institute (<http://genome.wustl.edu/>) at Washington University at St. Louis.

"The Genome Institute is a world leader in the fast-paced, constantly changing field of genomics. A truly unique institution, The Genome Institute is pushing the limits of academic research by creating, testing, and implementing new approaches to the study of biology with the goal of understanding human health and disease, as well as evolution and the biology of other organisms. As one of only 3 NIH funded large-scale sequencing centers in the US, The Genome Institute is helping to lead the way in high-speed, comprehensive genomics. Since its inception in 1993, The Genome Institute has played a vital role in the field of genome sequencing, receiving over \$800 million in funding. The Genome Institute began as a key player in the Human Genome Project – an international effort to decode all 3 billion letters of our genetic blueprint – ultimately contributing 25% of the finished sequence."

7) The Center for Bioethics (<http://www.med.upenn.edu/bioethics/about.shtml>) at the Univ of Penn.

"The Center for Bioethics is a leader in bioethics research and its deployment in the ethical, efficient, and compassionate practice of the life sciences and medicine. Interdisciplinary research in bioethics at Penn is located in the Center. Under the leadership of its founding director, Arthur L. Caplan, Ph.D., the Center has become a world-renowned educational and research enterprise that has appointed over 20 full and part-time faculty with appointments in a number of Univ of Penn schools and departments including medicine, law, nursing, business, education, philosophy, psychology, sociology, religious studies and public policy."