

Contact: Diana Gonzalez

**REQUEST TO CREATE NEW INSTITUTE AT THE UNIVERSITY OF IOWA:
IOWA INSTITUTE OF HUMAN GENETICS**

Action Requested: Consider approval of the request by the University of Iowa to establish an Iowa Institute of Human Genetics within the Carver College of Medicine.

Executive Summary: The purpose of the proposed Institute will be to promote basic clinical care, research, and education focused on the medical and scientific significance of variation in the human genome. This proposal was reviewed by the Board Office and the Council of Provosts and is recommended for approval. Board of Regents Policy Manual §6.08 requires that all centers and institutes be approved by the Board. This request addresses the Board of Regents Strategic Plan priorities to provide “educational excellence and impact” and “economic development and vitality” and Goal #7 “Iowa’s public universities shall contribute to the expansion and diversification of the Iowa economy” and Goal #8 “Iowa’s public universities and special schools shall be increasingly efficient and productive.”

Background:

- ◇ Description of proposed institute. The mission of the proposed Iowa Institute of Human Genetics (IIHG) is to create a world-renowned institute of excellence that integrates state-wide activities in human genetics that can be found in the university’s Colleges of Medicine, Engineering, Liberal Arts and Sciences, Law, Nursing, Pharmacy, Public Health, Education, and Dentistry.

The IIHG is dedicated to promoting clinical care, research, and education focused on the medical and scientific significance of variation in the human genome. Inherited and acquired variation in genome sequences are included, as are methods to change or add DNA sequences to human cells for therapeutic purposes (‘gene therapy’). The IIHG will also serve as a state-wide resource for outreach about issues related to understanding the extent and meaning of human DNA sequence variation. The IIHG will support and contribute to these goals by sponsoring pilot grants, symposia and workshops, teaching classes, and advising staff that run core facilities or control resources that are valuable for human genetics research.

The exponential growth in human genetics research is driving the increasing application of genetics in day-to-day medical practice. The unique environment of the IIHG at the University of Iowa will provide opportunities to make progress in both the discovery and translational phases of human genetics. It will also provide an interface with, and support for, university-wide activities related to human genetics. In particular, the IIHG will:

- ⇒ Provide genome-personalized clinical evaluations and consultations;
- ⇒ Offer genetic testing for a variety of common and rare diseases using state-of-the-art strategies, including targeted-genome capture and massively parallel sequencing;
- ⇒ Provide a resource for the management of common and rare congenital and inherited disorders;
- ⇒ Foster collaborations between clinicians and basic scientists to promote advances in human genetics;

- ⇒ Provide a collaborative environment for multidisciplinary research into the genetic bases of diseases;
- ⇒ Promote the use of gene therapy in both research and therapeutic applications;
- ⇒ Facilitate the translation of discoveries in human genetics into improved patient care;
- ⇒ Provide insights into the important ethical, social, and legal aspects of human genetics;
- ⇒ Offer patient/family oriented conferences focused on rare diseases (orphan diseases) to disseminate genetic knowledge and state-of-the-art care for these diseases.

- ◇ Activities and objectives of the proposed institute. The IIHG will integrate the research strengths of the University of Iowa with the clinical strengths of the Carver College of Medicine and provide to scientists and clinicians a state-of-the-art, high-throughput genetic analysis facility to support research and clinical activities focused on human genetics and personalized genomic medicine. The IIHG will have the expertise and resources to coordinate large-scale gene discovery, targeted gene-based and disease-based clinical diagnostics to improve disease-specific treatment, and pharmacogenomic-based prescribing to optimize drug-patient outcomes. The proposed institute will provide the following areas of emphasis:

Research:

- ⇒ Provide genetic core facilities to investigators at the University of Iowa.
- ⇒ Promote intra-institutional collaborations between clinicians and basic scientists.
- ⇒ Provide seed grants for human-genetics based research likely to impact personalized genomic medicine.

Clinical:

- ⇒ Rare diseases. Initial efforts will focus on the development of a state-of-the-art clinical genetics diagnostic platform that uses targeted-sequence capture and massively parallel sequencing to interrogate all genes implicated in rare renal diseases. This platform will expand and support the current Rare Renal Diseases Clinic in the Carver College of Medicine that is nationally and internationally renowned for its care of patients with two ultra-rare renal diseases, Dense Deposit Disease (DDD) and atypical Hemolytic Uremic Syndrome (aHUS). Future initiatives will target neurological diseases, cancer, diabetes, and other diseases as dictated by the needs of UIHC.
- ⇒ Drug therapy. Initial efforts will focus on the development of a pharmacogenetics-based platform to optimize favorable drug-patient outcomes and minimize unfavorable drug-patient outcomes.
- ⇒ Whole exome sequencing. The IIHG will provide whole exome sequencing (WES) on select patients to optimize their clinical care and health management.

Education:

- ⇒ Provide human genetics lectures in all clinical departments.
- ⇒ Participate in undergraduate and medical student human genetics education.
- ⇒ Offer a seminar series focused on human genetics and personalized medical care.

- ⇒ Provide outreach in the form of lectures to the public interested in learning how genomic information can influence their health care.

Future growth may include genetics initiatives focused on preventive medicine and 'wellness'; exome sequencing with disease-specific variant analysis; and exploring the implementation of new tools.

- ◇ Need for proposed institute. The proposed Institute will integrate state-wide activities in human genetics using an inter-disciplinary approach. It will address the need to focus clinical care, research, and education on the medical and scientific significance of variation in the human genome.

- ◇ Relationship of proposed Institute to University's strategic plan. The proposed Institute will address three of the four strategic priorities established in the University's 2010-2016 Strategic Plan:

- ⇒ As personalized medicine becomes a reality, students must understand how law, communications, risk assessment, and public policy impact prevention and treatment of common diseases. Each person's genetic background (a unique genome) can now be sequenced through advances in technology. A person's genome directly affects the risk for disease and response to therapies. While the identification of "risks and benefits" offers the promise of major clinical advances, it also creates challenges that range from personal risk assessment and insurability to views on race and ancestry, forensic testing, and database access. Educational programs sponsored by IIHG will inform students, clinicians, and the public about the potential risks and benefits of personalized medicine.
- ⇒ Genetics plays a key role in the knowledge and practice of public health and clinical care. The IIHG will help Iowa expand its strengths in genetic disease studies by playing a leadership role in facilitating the conversion of genetic knowledge to clinical use.
- ⇒ The IIHG will be integral to the health-life initiative for Iowans by promoting the use of personalized genomic medicine for more effective and personalized prescribing habits, treatments of cancer, aging, obesity, cardiovascular disease, pre-term birth, and other major public health challenges that are strongly influenced by genetics.

- ◇ Relationship of proposed Institute to existing centers/institutes. Immediate collaborations are expected with a number of existing centers/institutes, including the Center for Computer Aided Design, Holden Comprehensive Cancer Center, Cardiovascular Center, Fraternal Order of Eagles Diabetes Research Center, Center for Bioinformatics and Computational Biology, Iowa Center of Excellence in Image Guided Radiation Therapy, Iowa Center on Aging, and Institute for Clinical and Translational Science.

Close ties are anticipated between the IIHG and the Center for Bioinformatics and Computational Biology and the Institute for Clinical and Translational Science. The IIHG is expected to become one of the strong research and clinical directions of the university and the Carver College of Medicine and will provide expertise to and facilitate multi-faceted partnerships with other institutes and centers at the university and across the state.

- ◇ Unique role of the University of Iowa to support the proposed Institute. The University of Iowa is the ideal location for the IIHG because of the strengths and expertise offered by the Carver College of Medicine and the University of Iowa Hospitals and Clinics. The existence of cutting-edge genetics research at the University of Iowa has driven the need to create the IIHG.

The advances in genomic medicine coupled with those in computational biology and informatics are pushing personalized medicine to the mainstream. The IIHG will capitalize on these advances by expanding the area of human genetics as applied to personalized medicine by integrating genome-driven advances with large scale analytic platforms, computational biology, and bioinformatics. The University and the state of Iowa have strengths in several of these new developing, parallel and complementary fields; however, the communities are often fragmented with substantial gaps in needed expertise.

Since its creation five years ago, the Institute of Clinical and Translational Science (ICTS) has supported genetic research activities at the University. The ICTS has also embarked on a major effort to establish a biorepository connected to the UIHC's EPIC electronic medical records, which will enable investigators to conduct broad-based population research on the role of genetic and environmental factors in health and disease, with a particular focus on those disorders under intensive study at the University. These ICTS activities will serve as a strong central organizational entity for the translational aspects of the IIHG, illustrating the important partnership between the ICTS and IIHG.

The University of Iowa is the only university in the state that has the resources and synergies (e.g., clinical and research faculty, medical students, research programs, and clinical patient population) required to establish the IIHG.

- ◇ Relationship of proposed Institute to other Iowa institutions. Inter-institutional cooperation and collaboration will be incorporated into the function and structure of the IIHG. In particular, Iowa State University has outstanding programs, including world class animal genomics faculty, comparative genomics research, animal models for human disorders, additional bioinformatics capabilities, and additional DNA, RNA and sequencing capabilities. Coupling these strengths with the IIHG will create synergy and novel opportunities for collaboration between both universities. IIHG will develop programs to offer bioinformatics students at both universities the option of cross-rotations to broaden their educational experience. Co-mentorships of graduate students are also anticipated. To ensure open and mutually beneficial development, the IIHG will include two faculty from ISU on its Board of External Advisors who will serve with four other members from outlying states.

- ◇ Unique features of the University of Iowa. The IIHG will build upon distinct strengths of the University.

- ⇒ The IIHG will build on the existing strengths in genetics with a dedicated focus on human genetics, and, more specifically, the human genome and its integration into clinical medicine. The University has had a targeted program in genetics since the mid-1970s when the Interdisciplinary Program in Genetics was created. This program has united faculty with shared interests in genetics (not specifically human genetics) and continues to be a resource to attract and support graduate students with National Institutes of Health (NIH) and National Science Foundation (NSF) training grants. Currently, the Interdisciplinary Program in Genetics, consisting of

more than 60 faculty members, offers graduate-level courses independent of departments for pre-doctoral and advanced undergraduate students.

- ⇒ Clinical activities in genetics in the Carver College of Medicine expanded with the creation of the Interdisciplinary Program in Genetics to take advantage of advances in clinical diagnostics, including chromosome analysis and prenatal diagnosis. These advances have afforded direct clinical opportunities for diagnosing genetic diseases and improving patient care. During the past two decades, genetics in medicine has developed a significant presence, particularly in Pediatrics, Obstetrics, Psychiatry, Otolaryngology, and Ophthalmology. Exceptional programs of research in these departments with clinical and translational ties have enabled the University to acquire a national and international presence in many areas of genetic research. The IIHG will build on this foundation of excellence and specifically target individualized genomic medicine to provide personalized medical care.
- ⇒ The ICTS and the IIHG offer the potential for strong synergy. Since its inception five years ago, the ICTS has supported genetic research activities at the University. It is embarking on a major effort to establish a biorepository connected to the EPIC electronic medical records which will be integral to initiatives by the IIHG in such areas as pharmaco-genomics. ICTS will provide a strong central organizational entity for the translational aspects of the IIHG and will be an important partner in the development of personalized genomic medicine.

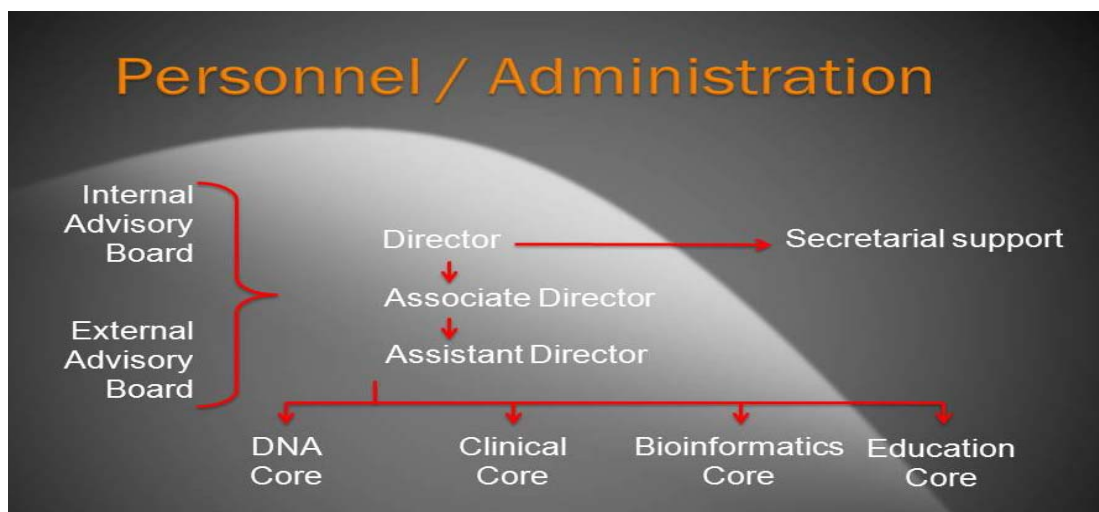
The proposed Institute will also have the capacity to address significant gaps in human genetics at the University.

- ⇒ In the area of common adult diseases, such as cancer, there is a need to have a genetic presence to take advantage of the opportunities available through the Holden Comprehensive Cancer Center. Other adult disorders and areas of research with translational opportunities include obesity, diabetes, cardiovascular disease, and women's health.
- ⇒ Cutting edge research in personalized genomic medicine requires strong computational biology and informatics. This need creates both opportunities and challenges that arise from the volume of genetic data, its associated large scale technologies and analytic needs, computational biology and bioinformatics, and the framework for the collection and management of large and diverse datasets. The University has strengths in several aspects of these newly developing fields, although the communities are fragmented. The IIHG will address these issues by developing an integrated pipeline for data generation and analysis built initially on the interpretation of human genomic data in the context of its translational impact on improved medical care.

The University also anticipates significant synergies with a number of training programs.

- ⇒ *T32 Genetics, Predoctoral Training Program.* The Genetics Ph.D. Program at the University is a broad based interdisciplinary program that incorporates cutting-edge techniques to answer the foremost questions facing biology, medicine, evolution, and bioinformatics. This program is designed to provide both a core curriculum in Genetics and sufficient flexibility to fit students' individual needs. It provides research opportunities across the spectrum of genetics and fosters strong independent thinking to equip students to meet modern challenges of doctoral graduates.

- ⇒ *T32 Computational Biology Predoctoral Training Program.* The program supervisor has joint appointments in the Colleges of Engineering and Medicine and accepts students with either a computational or biological sciences background into a Ph.D. program that provides training in both. The goal is to create a cadre of new investigators fluent in both biology and computer sciences who can work at the interface of genetic analysis, technology, and disease.
- ⇒ *TL1 Program, Institute for Clinical and Translational Science.* This program facilitates the training of scholars in Ph.D. programs in translational science.
- ◇ Proposed Institute structure and organization. The proposed Institute will have a director, an associate director, and an assistant director. The associate and assistant directors are current faculty who will be assigned on a part-time basis to the Institute. There will be 10 DNA employees, the majority of whom are current employees who will be re-assigned to the Institute; 8.6 clinic employees including a genetic counselor, research specialists, as well as students who will be hired in the future; and 5.1 bioinformatics employees, the majority of whom will be hired in the future. The total number of Institute employees is projected to be 24.1 FTE.



- ◇ External advisory board. The purpose of the external advisory board will be to review biannual goals of the proposed Institute; assess milestones; and evaluate future initiatives. The membership will include six representatives, including two from Iowa State University, and four out-of-state members recommended by the Internal Advisory Board.
- ◇ Resources. No new equipment is anticipated for the proposed Institute because it is already in place and will be consolidated with the existing DNA sequencing Core. The purchase of additional equipment in the future will be dependent on the volume of contracted work and its accompanying revenue.

The proposed Institute will be housed initially in the current DNA sequencing Core space. As services expand, new space may be identified to consolidate all the research and clinically related work in one space.

- ◇ Expected need. The proposed Institute is expected to be in existence for the foreseeable future. It will be evaluated on an annual basis for progress on developmental milestones and formally reviewed every five years by a panel of unaffiliated external reviewers. The results of the evaluations will be used for program improvements.
- ◇ Costs and funding sources. The Carver College of Medicine has committed \$5 million from the Helen Johnson Endowment to support the Institute. The revenue generated by clinical and laboratory activities, such as whole exome sequencing, in addition to College support, is anticipated to provide sufficient revenue to cover the expenses of the proposed Institute. The IHG is expected to be entirely self-sufficient able to function independently of College support by Year 6.

**PROPOSED REVENUES AND EXPENDITURES
IOWA INSTITUTE OF HUMAN GENETICS**

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
REVENUE					
DNA/Bioinformatics Revenue ¹	\$1,684,136	\$1,902,550	\$2,273,060	\$2,495,366	\$2,739,902
Clinic Revenue ²		\$250,000	\$450,000	\$600,000	\$900,000
Grants and Institutional Support ³	\$136,177	\$140,491	\$249,597	\$256,405	\$263,404
CCOM Startup Support ⁴	\$1,324,274	\$1,341,244	\$858,730	\$838,086	\$365,606
TOTAL REVENUE	\$3,144,587	\$3,634,284	\$3,831,387	\$4,189,857	\$4,268,913
OPERATING EXPENSES					
Administration	\$40,579	\$62,695	\$107,409	\$110,410	\$113,497
DNA Expenses	\$1,852,200	\$1,923,049	\$1,962,336	\$2,115,748	\$2,186,462
Clinic Expenses	\$511,355	\$844,159	\$888,433	\$1,024,149	\$1,062,255
Bioinformatics	\$515,454	\$579,381	\$648,209	\$714,550	\$681,698
Other	\$225,000	\$225,000	\$225,000	\$225,000	\$225,000
TOTAL OPERATING EXPENSES	\$3,144,587	\$3,634,284	\$3,831,387	\$4,189,857	\$4,268,913

- ◇ Implementation. After obtaining Board approval, the Carver College of Medicine is prepared to implement the Institute in Fall 2012.

¹ Revenue for services rendered to investigators requesting DNA-sequencing and analytical work related to research funded by their extramural grants.

² Revenue from external providers or insurance companies for medically necessary services related to patient care. Referrals will be received from community providers and UIHC providers.

³ Revenue reflects direct offset of salary costs for faculty and staff of the Institute from their own extramurally funded grants or other institutional resources, such as endowed chairs, or other external resources earmarked for faculty working in the Institute. No reallocations of existing General Education Funds from other units are planned.

⁴ Revenue reflects time-limited support from the CCOM to bridge the Institute until other revenue streams are sufficient to cover the Institute costs, projected to occur by Year 6. Source of funds will be central College tax on practice plan clinical revenue and gifts received by the College.