Consortium on Law and Values in Health, Environment & the Life Sciences™
University of Minnesota

Pioneering Study Will Establish the Legal Framework for Genomic Medicine

Eminent researchers are awarded a 3-year, $2M NIH grant

FOR IMMEDIATE RELEASE

Media Contact: Kathryn Grimes
Consortium on Law and Values in Health, Environment & the Life Sciences
grime002@umn.edu | 612-625-2948

MINNEAPOLIS – The National Institutes of Health (NIH) has awarded the first-ever grant dedicated to laying the policy groundwork needed to translate genomic medicine into clinical application. The project – **LawSeq**[SM] – will convene legal, ethics and scientific experts from across the country to analyze what the state of genomic law *is* and create much-needed guidance on what it *should be*.

NIH has declared the adoption of genomic medicine by clinicians to be a top priority to improve both individual and public health. The federal Precision Medicine Initiative (PMI), announced by President Obama and currently being launched, aims to use genomics and other analyses to accelerate development of more powerful and tailored treatments for cancer and other diseases. Yet U.S. federal and state genomics law is unclear and poorly understood, presenting a major obstacle to progress.

As NIH Director Francis S. Collins, MD, and National Cancer Institute Director Harold Varmus, MD, have written, "Achieving the goals of precision medicine will . . . require advancing the nation's regulatory frameworks." Leading LawSeq[SM] is a team of three principal investigators:

- **Susan M. Wolf, JD** (University of Minnesota) is an expert on law, medicine and public policy who, for more than a decade, has led a succession of NIH-funded projects generating recommendations on return of research results and incidental findings in genomics.
- **Ellen Wright Clayton, MD, JD** (Vanderbilt University) is an expert on the ethical, legal and policy questions raised by genomics, who has led NIH-funded work on pediatric genomics and co-directs an NIH-funded Center of Excellence in Genomic Science.
- **Frances Lawrenz, PhD** (University of Minnesota) is an expert in qualitative and quantitative research methods who has successfully led multiple National Science Foundation grants and has directed qualitative research on managing incidental findings and return of genomic results.

These co-leaders will be joined by a group of 22 top experts – from academia, industry, and clinical care – who will collaborate over the course of this 3-year project to clarify current law, address gaps, and generate the forward-looking recommendations needed to create the legal foundation for successfully translating genomics into clinical care.

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LawSeq℠
Mapping & Shaping the Law of Genomics