## Toward Pharmacogenomics-Enabled Healthcare at Statewide Scale: Implementing Precision Medicine

## EXECUTIVE SUMMARY

The objective of this Grand Challenge is to bring the benefits of a healthcare innovation, pharmacogenomics (PGx), to patients at a large scale using Minnesota (MN) as a statewide laboratory for PGx implementation science and a research platform for future research. This project leverages the work by these PIs in a Grand Challenge 1 project where precision medicine projects were successfully launched in minority and underrepresented populations and continue to grow. Successful teams were built, relationships and programs were created. This allows us now to implement PGx in clinical care, the most mature domain of precision medicine.

PGx tailors the choice and dose of pharmaceutical treatments based on individuals' genetic characteristics. Inherently interdisciplinary, PGx is driven by pharmacology and genetics but several additional dimensions are essential for its successful implementation, including scientific expertise, information technology and informatics, health economics, and ethical, legal, and social issues (ELSI). Selection of medications based on the genetic profile of individual patients will increase medication effectiveness and safety, improve the patient experience, and reduce health care costs, while limiting drug-related side effects. PGx is a hallmark of the National Precision Medicine Initiative, but wide-scale implementation is challenging. Only fragmented implementation approaches within single health systems have been attempted in the state and across the nation. Our proposed project is multidisciplinary, highly collaborative and will create a framework for statewide implementation that will affect multiple health systems caring for millions of patients. We will partner with scientists, clinicians, ELSI experts, business professionals, state government authorities and students to apply scientific and clinical expertise, informatics technologies, health economics knowledge, leadership in policy and ELSI. This project will partner with health systems in the state who are early adopters of PGx (i.e., Mayo and Children's Minnesota) and have successfully launched programs. Partnerships between early adopters and those not yet (or in the process of) adopting PGx innovation will accelerate implementation and bring the benefits to our state through adoption of best practices.

Our team will engage stakeholders to create a roadmap and policy framework for eventual statewide PGx innovation adoption and clinical implementation. We will do this by I) assembling and codifying best practices for evidence-driven PGx implementation, practice and innovation; 2) forming a PGx Expert Committee to evaluate and recommend drug-gene pairs and gene panels for implementation; 3) collecting evidence and working with payers to establish the health economic value of PGx; 4) designing and prototyping EHR integration and clinical decision support (CDS) systems to deliver PGx test results and interpretation, with high-security barriers against data privacy threats; 5) establishing a PGx Education Task Force to assess educational needs for the state's workforce, students, policy makers, healthcare systems, and payers; 6) creating a PGx ELSI task force to address barriers to PGx at the state level; 7) creating the foundations for PGx research at state scale; and 8) deploying two demonstration PGx implementation projects (in oncology and psychiatry) to show feasibility for ultimate statewide deployment.

We will engage and work with policy makers and others to promote this statewide approach to implementation, advocate for state funding and seek national funding. We will continue to advance our Minnesota Precision Medicine Collaborative research engagement work from Phase I with underserved and minority populations, serving populations disproportionately affected by adverse medication events that are preventable through PGx. The project will develop educational opportunities for students and the health workforce and will set the stage for future research that will extend the present body of PGx knowledge. Strong partnerships established in this proposal will drive PGx adoption and implementation in the state while creating a unique research resource and a model for other states. Matching funds (\$50,000) have been committed from the College of Pharmacy and the Medical School.