

Precision Medicine and the Changing Landscape of Research Ethics

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President Barack Obama announced the launch of the National Institutes of Health Precision Medicine Initiative® (PMI) in January 2015 (Whitehouse.gov, 2015). Precision medicine includes the concept of individualized or personalized medicine at a more exact level through advances in science and technology, such as genetics and genomics sequencing (Ashley, 2015; Fiore & Goodman, 2015). Although many disease processes will be investigated through the precision medicine lens for greater understanding and improved treatment responses, oncology research and translation to practice is leading the initiative's debut, referred to as the near-term focus (Collins & Varmus, 2015; Fiore & Goodman, 2015).

Ethical Practice in Genetics and Genomics

In effect, the PMI is further propagating the already exponentially evolving rate of genetics and genomics research. The overarching results are anticipated to vastly change the health and well-being of humankind for the better, so that we may live more enjoyable, productive, and longer lives.

However, the path to healthier lives through the emphasis of genetics and genomics research raises new challenges on an ethical scale. The protection of human participants in research studies, including genetics and genomics

investigations, is governed under the federal regulation code known as the Common Rule (National Human Genome Institute [NHGI], 2015). In general, ethical research aims to generate new knowledge to guide the implementation of new or improved interventions and treatments, as well as evaluation of those interventions and treatments, for improved health outcomes and to ensure that individuals are well informed about study participation, including risks and benefits (NHGI, 2015). In addition, the Common Rule ensures that privacy and confidentiality are maintained (Fiore & Goodman, 2015).

Issues Facing Genetics and Genomics Research

A major challenge with genetics and genomics research is that it is a nascent science still being refined and opening doors to new questions and issues. In addition, part of the PMI is to include patients as active partners in research, giving them access to the study outcomes to which they contribute (Collins & Varmus, 2015). Achieving the PMI's goals while maintaining the tenets of protecting human participants may require some changes to the Common Rule (Collins & Varmus, 2015; Fiore & Goodman, 2015) and a push toward broad consent, meaning a global consent form that would not have to be tailored to individual studies (Fiore & Goodman, 2015).