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ACMG Provides Guidance on Protecting Patient Genomic Data and Avoiding Unfair Discrimination and Misuse of Genetic Information

BETHESDA, MD – December 16, 2021 | The American College of Medical Genetics and Genomics (ACMG) has just released two highly-anticipated companion documents, "Stewardship of Patient Genomic Data: A Policy Statement of the ACMG" as well as "Points to Consider to Avoid Unfair Discrimination and the Misuse of Genetic Information: A Statement of the American College of Medical Genetics and Genomics."

As a leader in advancing genomic medicine, the ACMG is committed to educating the public on the benefits and risks of genetic testing, as well as protecting and preserving patients' welfare, autonomy and privacy.

"Genomic information and data sharing is essential to improving the quality of care for our patients and disseminating knowledge in a field that is rapidly advancing," said ACMG President Marc S. Williams, MD, FACMG. "However, there is the potential for misuse of this information that can lead to harms. These two documents address the balance of benefits and harms and provide guidance to inform solutions that can enhance the benefits of sharing genetic information while minimizing risk to our patients."

ACMG noted in its **Policy Statement** that the exchange of de-identified genomic data represents a potential avenue for breach of privacy that is inadequately protected by prevailing regulations and norms of practice. Consequently, the ACMG determined that there is a compelling need to establish standards of practice around the sale, transfer or exchange of human clinical and genetic information to ensure the welfare of patients and community members in terms of privacy, consent and the public's trust.

In the **Policy Statement**, the ACMG defined eight key elements related to the use, transfer and sale of de-identified patient or consumer data obtained through the process of screening or diagnostic testing. These elements cover such areas as patient notification/consent, the responsibilities of testing laboratories, data use agreements and the resale or transfer of genomic data.

"In light of remarkable advances in genomic technologies and bioinformatics that brings medical genetics ever closer to the center of medicine, we recognized a growing need to make explicit the ethical obligations that geneticists and care providers have to act as stewards over the samples and information entrusted

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to us by patients and members of the general public," said Policy Statement lead author Robert G. Best, PhD, FACMG. "Protecting the welfare, autonomy and privacy of those who depend upon us for their care is essential to the vision of ACMG as we empower our members to be leaders in the integration of genetics and genomics into all of medicine and healthcare for the advancement of personal and public health."

While this policy is primarily directed toward the sharing of genetic data and samples received by a clinical laboratory with outside entities, the College encourages full transparency with patients and consumers in connection with the many ways that patient samples and data are integrated into laboratory processes such as quality assurance, test development and knowledge sharing through public genomic data repositories.

Laurie H. Seaver, MD, FACMG and lead author of the **Points to Consider Statement** said, "The original ACMG Points to Consider (PTC) document relating to Unfair Genetic Discrimination was published 20 years ago. Given the widespread use of genetic testing for medical and non-medical uses, the ACMG Social, Ethical and Legal Issues (SELI) committee thought it was important to once again address concerns about the potential for unfair genetic discrimination. Our diverse working group included representative voices of clinical genetics, laboratory genetics, genetic counseling, bioethics, law, and families/consumers. We began our work by reviewing and summarizing pertinent legislation which focuses on employment and health insurance, but then expanded our scope by highlighting issues of social justice, life and disability insurance and the importance of privacy and security in preventing misuse of genetic information and unfair genetic discrimination."

The **Points to Consider Statement** concludes that advances in our understanding of human health and disease are now often based on shared genomic data. Attention must then focus on proper and just use of this data for both the individual and society, recognizing that the data might be used to unfairly discriminate now or in the future; and that strategies must be developed to prevent or mitigate such misuse. ACMG noted the need to be sensitive to both real and perceived concerns about genetic discrimination and the importance of a detailed informed consent conversation, addressing the use of genetic data and any privacy concerns, for any genetic testing. The statement also concludes that robust federal legislation protecting the privacy and security of genetic information is critical; and emphasizes the need to actively work to increase the diversity of reference databases as well as the diversity of the genetics workforce.

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The ACMG recognizes that genetic information also has the potential to contribute to unfair discrimination in other areas of society such as education, housing, finance and law enforcement. As such, the ACMG knows it plays a critical role in identifying and helping to prevent unfair genetic discrimination and will continue its advocacy to this end.

"Advances in our understanding of human health and disease are based on shared genomic data. We must focus on proper and just use of this data for both the individual and society, recognizing how the data might be used to unfairly discriminate now and, in the future, and develop strategies to prevent or mitigate such misuse," concluded Dr. Seaver. "These ACMG documents will provide a framework for further policy, practice and legislation related to genetic information.

About the American College of Medical Genetics and Genomics (ACMG) and ACMG Foundation

Founded in 1991, the American College of Medical Genetics and Genomics (ACMG) is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is the largest membership organization specifically for medical geneticists, providing education, resources and a voice for more than 2,400 clinical and laboratory geneticists, genetic counselors and other healthcare professionals, nearly 80% of whom are board certified in the medical genetics specialties. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health. Four overarching strategies guide ACMG's work: 1) to reinforce and expand ACMG's position as the leader and prominent authority in the field of medical genetics and genomics, including clinical research, while educating the medical community on the significant role that genetics and genomics will continue to play in understanding, preventing, treating and curing disease; 2) to secure and expand the professional workforce for medical genetics and genomics; 3) to advocate for the specialty; and 4) to provide best-in-class education to members and nonmembers. *Genetics in Medicine*, published monthly, is the official ACMG journal. ACMG's website, www.acmg.net offers resources including policy statements, practice guidelines, educational programs and a 'Find a Genetic Service' tool. The educational and public health programs of the ACMG are dependent upon charitable gifts from corporations, foundations and individuals through the ACMG Foundation for Genetic and Genomic Medicine.

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