



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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October 24, 2017

Jeffrey R. Botkin, MD, MPH

Chair, Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories,
The National Academies of Sciences, Health, and Medicine

Associate Vice President for Research Integrity and Chief, Medical Ethics

University of Utah School of Medicine

50 North Medical Drive

Salt Lake City, UT 84132

Dear Dr. Botkin:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the return of individual-specific research results generated in research laboratories. AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics (IVD) industry.

AMP would like to express support for the principles and considerations conveyed in the letter submitted by the American Society for Investigational Pathology (ASIP). We respectfully request the Committee seriously consider the points raised in this letter as you develop your recommendations and final report. A major tenet of the ASIP letter is that laboratories providing results to be used in patient care should be CLIA-certified. AMP strongly supports this position and reiterates that any results that will be used in patient care should be derived or confirmed by a CLIA-certified laboratory. Below, AMP underscores a few other key points, which we feel deserve further explanation and emphasis.

AMP is unequivocally supportive of patients having a central and significant role in the direction of their care and believes that patient access to clinically relevant information is a right that should be protected. However, there are vast and critical differences between how testing is performed and results are interpreted and reported in research and clinical laboratories that warrant the inclusion of a CLIA-certified laboratory in this process. CLIA-certified laboratories incorporate multiple strata of quality control and quality assurance practices not required by research laboratories. The acquisition of research data is not held to the same scrutiny as the processes of clinical laboratories and, as a result, testing performed in a non CLIA-certified laboratory presents a greater possibility for pre-analytic and analytic and reporting errors, such as, but not limited to specimen labeling and tracking errors. There are also significant differences in interpretation of genetic results between qualified clinical laboratory professionals and research personnel. These potential errors could cause significant harm for participants and their families. For example, if there is a sample mix-up in a research laboratory, the participants would receive incorrect results. Additionally, if a genetic variant is

misclassified by a research laboratory, this could have a negative impact in the clinical care of the participant and their family members. For example, a variant of uncertain significance could be misclassified by a research laboratory as *likely pathogenic*; any family members who would not test positive for this *likely pathogenic* variant would be considered to not be at-risk for the disorder and may not receive proper screenings or care. Thus, the return of individual research results from research laboratories that do not adhere to clinical standards of testing should be generally discouraged.

In addition, we agree with ASIP that releasing individual results would require an enormous increase in administrative burden on researchers and make research laboratories subject to litigation with regards to genetic variant classification and interpretation. There is an enormous amount of expertise and infrastructure that is needed to communicate a clinically relevant result. AMP believes that researchers and other study investigators should not directly deliver results to participants but rather, a participant's treating physician or another appropriately credentialed healthcare professional should communicate results. Research laboratories are typically not prepared for the associated responsibilities of providing participants with medical information, such as ensuring that appropriate follow-up evaluation and treatment are provided and accessible to the patient. Involving an appropriately credentialed healthcare professional prevents laboratories from having to adopt and duplicate aspects of patient care.

Care should be taken as the Committee develops their recommendations to retain clear distinctions between research and clinical practice so that they can both flourish and improve our abilities to obtain information that can better patients' lives.

We appreciate the opportunity to express our concerns to you and the Committee. If you have any questions, please feel free to contact Tara Burke, Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Federico A. Monzon, MD
President, Association for Molecular Pathology