

June 26, 2019

Francis Collins, MD, PhD
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Griffin P. Rodgers, MD, MACP
Director, National Institute of Diabetes and
Digestive and Kidney Diseases
9000 Rockville Pike
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Dear Dr. Collins, Dr. Rodgers, and Members of the Clinical Center Governing Board,

On behalf of the Endocrine Society, I am writing to you today to share our concern regarding potential alterations to the Metabolic Clinical Research Unit (MCRU) at the National Institutes of Health (NIH) Clinical Center. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. The Society's membership of over 18,000 includes biomedical researchers who are dedicated to studying the underlying causes of metabolic disorders, including obesity and type-2 diabetes, and ensuring that individuals with these and other disorders receive care based on the latest scientific evidence.

The Endocrine Society recently learned of preliminary discussions to close or significantly alter the function of the MCRU and relocate patients participating in clinical studies on metabolic disorders in order to create space for other areas of clinical research. We appreciate that NIH must balance many competing priorities and advance research on diverse public health issues; however, we are concerned that reducing the operations of the MCRU, or relocating participants to areas without a concentration of specialized resources, sends a troubling signal that research on diabetes, obesity, and metabolic disorders are not a high priority for the NIH. These conditions represent a serious public health emergency, and they are also often related to other chronic diseases and comorbidities. Currently, more than one in three adults in the United States are obese, and more than 100 million adults are now living with diabetes or prediabetes. These dramatic statistics lead to significant medical expenditures for individual patients as well as the health care system as a whole.

The highly specialized resources present at the MCRU are designed to support cutting-edge clinical trials involving participants with complex metabolic conditions. The Human Energy and Body Weight Regulation Core co-located with the Nutrition Research Services and other clinical support allow the conduct of studies with strict control over diet, physical activity, and environmental conditions. The concentration of resources related to metabolic phenotyping (e.g., stable isotope infusions, glycemic clamps) has catalyzed many important studies relevant to common forms of obesity and diabetes in both adults and children, as well as rare endocrine disorders such as lipodystrophy. This and other unique features of the MCRU, such as whole room calorimetry for evaluating metabolism, cannot be replicated elsewhere at the NIH. Staff at the MCRU are also highly trained individuals with expertise needed to ensure that study protocols are carried out with high precision and to ensure safety for patients and volunteers.



In addition to having the ability to carry out extremely specific and technical research, studies supported by the MCRU impact many fields of research and disciplines beyond diabetes and obesity. The MCRU fosters collaborations between the intramural research program and extramural researchers, who may not have local access to similar facilities. Our understanding is that closing or relocating functions currently within the MCRU would effectively end research studies that are ready to be initiated or already in progress. This would be a great loss for the endocrine research community; studies conducted at MCRU facilities has produced impactful research, for example demonstrating efficacy of recombinant leptin to reduce metabolic issues in patients with lipodystrophy¹, explaining racial differences in the development of fasting hyperglycemia², developing strategies to improve metabolic function in children³, and the effects of ultra-processed diets on weight gain⁴.

In conclusion, *the Endocrine Society asks NIH and Clinical Center leadership to continue to support the operation of the MCRU in its current state* to advance important research on priority areas such as diabetes, obesity, and metabolic disorders. This research opportunity cannot adequately be replaced elsewhere, and our members benefit from the excellent scientific output from the unit and from the ability to collaborate with intramural researchers at the MCRU.

Thank you for considering our comments. If we can be of any further assistance in your efforts, please contact Joseph Laakso, Ph.D., Director of Science Policy at jlaakso@endocrine.org

Sincerely,

E. Dale Abel, MB.BS., D.Phil. (M.D., Ph.D.)
President, Endocrine Society

¹ Brown RJ et al., Metreleptin-mediated improvements in insulin sensitivity are independent of food intake in humans with lipodystrophy. JCI 2018 (PMID: 29723161)

² Chung ST et al., Gluconeogenesis and risk for fasting hyperglycemia in black and white women. JCI Insight 2018 (PMID: 30232289)

³ Belcher, BR, et al., Effects of Interrupting Children's Sedentary Behaviors With Activity on Metabolic Function: A Randomized Trial, The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 10, 1 October 2015, Pages 3735–3743, <https://doi.org/10.1210/jc.2015-2803>

⁴ Hall KD et al., Ultra-processed diets cause excess calorie intake and weight gain: an inpatient randomized controlled trial of ad libitum food intake. Cell Metabolism 2019 (PMID: 31105044)