

June 20, 2019

Francis S. Collins, M.D., Ph.D. Director, National Institutes of Health (NIH) Bldg. 1 9000 Rockville Pike Bethesda, MD 20892

Griffin P. Rodgers, M.D., M.A.C.P Director, NIH National Institute of Diabetes and Digestive and Kidney Diseases Bldg. 31, Rm. 9A52 9000 Rockville Pike Bethesda, MD 20892-2560

Re: Proposed NIH Metabolic Clinical Research Unit Closure and Relocation of Functions

Dear Drs. Collins, Rodgers and NIH Clinical Center Governing Board members:

The American Society for Nutrition (ASN) appreciates the opportunity to submit comments to the NIH and the NIH Clinical Center regarding the NIH Metabolic Clinical Research Unit (MCRU) within the Clinical Center. Established in 1928, ASN is the preeminent nutrition research and practice organization reaching more than 35 million individuals each year with science-based nutrition information, education, and advocacy activities to advance global public health. ASN brings together the world's top researchers to advance the knowledge and application of nutrition. ASN has more than 6,500 members working in academia, public health, clinical practice, industry, and government who enhance scientific knowledge and quality of life through excellence in nutrition research and practice.

ASN recently learned of proposed plans to close the MRCU and relocate the MCRU's functions elsewhere in the Clinical Center, purportedly to make room for clinical studies related to Alzheimer's disease and opioid addiction. While ASN supports additional clinical research to better understand and mitigate the significant public health challenges related to both Alzheimer's disease and opioid addiction, ASN does not support closure of the MCRU or relocation of the MCRU's functions elsewhere at NIH or in the Clinical Center. Established in 2007, the MCRU studies human metabolism in subjects with various metabolic conditions, including obesity, diabetes, liver diseases, rare genetic conditions, neurological disorders, and cancers. Nutrition research studies conducted at the MCRU have investigated topics such as the effect of dietary fat and carbohydrate restriction in people with obesity, glucose and lipid homeostasis and inflammation, ad libitum food intake, physical activity and weight loss, energy expenditure, and metabolic adaptation to name a few.

The MCRU houses specialized, state-of-the-art facilities for comprehensive, critically

important studies of human nutrition that are not replicated elsewhere at NIH. The facilities at the MCRU include a metabolic kitchen, specially designed fitness equipment and other study resources such as body composition measurement tools and dietary, physical activity, and environmental assessment capabilities. These facilities also include adaptations that enable highly specific medical testing. For example, the MCRU was expressly designed to safely and comfortably accommodate study volunteers with up to class 3 obesity, who are most at risk for developing comorbidities. Absent the specialized structural accommodations that currently exist at the MCRU, investigation of patients with class 3 obesity will likely pose unnecessary and significant safety risks to study volunteers.

Facilities at other NIH Institutes/ Centers do not allow for such exacting conditions which would severely compromise diet adherence and other factors vital to ensure the scientific rigor and high quality of the nutrition research currently conducted at the MCRU. Without the highly trained, dedicated MCRU staff and the safety features integrated into the design of the MCRU, use of other facilities, including other areas of the Clinical Center, for such research could risk the safety of the study volunteers when performing testing such as bedside indirect calorimetry, tissue biopsies, frequent blood sampling, meal tolerance tests and intravenous tolerance tests.

The MCRU and the nutrition research conducted there generates new knowledge regarding the physiology, prevention, and treatment of obesity, type 2 diabetes, and other nutrition-related health issues, and brings together experts from numerous fields that touch on human nutrition, including metabolism, endocrinology, gastroenterology, hepatology, genetics, and the behavioral sciences. Many successful collaborations between NIH intramural investigators and the extramural scientific community have utilized the MCRU, including the first multi-site metabolic ward study using metabolic chambers. Overall, there are over twenty separate protocols that use the MCRU, led by groups from 6 different Institutes, as well as extramural investigators targeting more than 4,000 patients. Nearly every protocol requires support from the dedicated MCRU nurses, nutrition and support staff; support which is not replicable elsewhere in the Clinical Center.

The MCRU represents an ideal facility for multi-disciplinary research required to address nutrition-related public health challenges. Absent the type and quality of data collected in the MCRU, it is not possible to understand the relevance of animal and cell model approaches to the study of metabolism, obesity and type 2 diabetes. Given the high prevalence of these chronic diseases and their enormous health and economic burdens, closure of the MCRU or relocation of MCRU functions will negatively impact scientific advancements to combat these diseases and result in significant costs to public health.

Of utmost concern to ASN is that closure of the MCRU or relocation of MCRU functions effectively terminates several important areas of nutrition research that are either planned or actively underway including research on the effect of various diets on energy metabolism and brain dopamine function in obesity. Furthermore, the highly impactful work of intramural NIH

investigators who utilize the MCRU facilities, many who are ASN members, and the highly trained MCRU staff will be severely limited or worse, terminated. Closure of the MCRU or relocation of MCRU functions represents an immense loss of investment by the NIH and introduces a significant risk in terms of employee retention and recruitment. It is important that the NIH Clinical Center acknowledge the vital nutrition research being conducted at the MCRU to continue to recruit cutting-edge nutrition researchers to the NIH. Training the next generation of nutrition researchers is of utmost importance, and the specialized equipment and expertise of the MCRU staff and researchers will enable trainees from all over the globe to acquire the skills and experience necessary to develop their own careers aimed at tackling the major nutrition-related health issues of today.

Nutrition is an important, cross-cutting research priority that allows many promising opportunities for interdisciplinary research. However, closure of the MCRU or relocation of MCRU functions indicates that important nutrition research on topics such as obesity and type 2 diabetes are not priorities of the NIH intramural research program. The closure of the MCRU or relocation of MCRU functions does not clearly convey the importance of nutrition research at NIH to the external research community and indicates that nutrition research is not considered a prominent area of scientific pursuit at NIH, which is in direct opposition to the NIH's soon-to-be-unveiled Strategic Plan for Nutrition Research.

As the agency responsible for conducting and supporting 90% of all federally funded basic and clinical nutrition research, the NIH has profound effects on nutrition research and monitoring and the health of all Americans. As a strong advocate for NIH funding, ASN recognizes that some of the most promising nutrition-related research discoveries have been made possible by NIH support. We encourage the NIH to allow the MCRU to continue to operate in its current state to ensure critically important nutrition research that cannot be adequately conducted elsewhere is maintained and supported by the NIH.

Thank you for the opportunity to submit comments to NIH regarding the MCRU. Please contact Sarah Ohlhorst, M.S., R.D., Senior Director of Advocacy and Science Policy at 240-428-3647 or sohlhorst@nutrition.org if ASN may provide further assistance.

Sincerely,

Catherine J. Field, PhD, RD

Catherine J Field

2018-2019 President, American Society for Nutrition