M SQUARED
ASSOCIATES, INC.

April 19, 2021

ERC Program
Division of Engineering Education and Centers
National Science Foundation
4201 Wilson Boulevard
Arlington, Virginia 22230

Re: Columbia University proposal in response to NSF 20-553: Gen-4 Engineering Research Centers (ERC) – Convergent Research and Innovation through Inclusive Partnerships and Workforce Development

Dear ERC Program Directors,

If the proposal submitted by Dr. X. Edward Guo entitled *NSF Engineering Research Center for Integrated Mechanobiology for Women's Health (IMWEL)* is selected for funding by NSF, it is my intent to collaborate and/or commit resources as detailed in the Project Description or the Facilities, Equipment and Other Resources section of the proposal.

Since 2001, M Squared Associates (M2) has provided a full range of regulatory, clinical and quality consulting services to US and international medical technology firms. We specialize in devices, biologics and combination products that are reviewed by global regulatory agencies. Our services provide strategic pathways in support of our clients bringing new products to market, working with a large segment of the industry ranging from the small entrepreneurial to many industry leaders and academic medical centers. Our project strategies are based on a business-oriented approach; we take care to understand each client's US and global objectives to assure that the regulatory strategy compliments and supports plans for international commercialization. Our corporate culture fosters innovative thinking; we thrive on the complicated and complex regulatory challenges that are commonly associated with the most ground-breaking technologies. We have extensive experience across myriad disease spaces and therapeutic areas.

Regulatory affairs services range from regulatory strategy road-mapping and support at earlier stages of product development to preparation of formal submissions to global regulatory agencies such as FDA. Our clinical affairs program provides development and deployment of clinical research, study design, protocol authoring, biostatistical expertise and study management oversight. During product development and post-market activities, our Quality Systems specialists help design and implement compliant Quality Management Systems, Quality Plans, Quality Manuals and SOPs and prepare clients for Agency regulatory and clinical audits.

Sincerely,

Marie Marlow
Chief Executive Officer

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