Sleep Health and Consumer Technologies: A Position Statement from the National Sleep Foundation

The National Sleep Foundation (NSF) is dedicated to improving health and well-being for individuals of all ages through sleep education and advocacy. NSF recognizes that innovative tools designed to help improve people's sleep can have a real impact in advancing this mission. NSF considers products and services in scope for its SleepTech® activities collectively to be those that incorporate sleep science and know-how with the intention of helping people achieve and maintain healthy sleep. Products such as wearable and in-room sleep trackers, digital solutions, electronics and appliances, home goods, and structural and design features of the built environment, are increasingly used by the public. Advances in artificial intelligence, sensor technology, and biotechnology represent powerful opportunities to help achieve NSF's goal to rapidly incorporate sleep science and insight into accessible products and services. Products that are regulated as medical hardware or software for clinical use with patients are not within the scope of this NSF position on consumer products.

It is the position of the National Sleep Foundation that the appropriate use of science-backed and evidence-based consumer technology products and services for sleep may improve public health and help anyone and everyone be their Best Slept Self®.

Consumer technology for sleep health is a promising tool and growing category for enhancing sleep and addressing various sleep-related issues, so NSF serves a critical function in engaging with the public, policymakers, researchers, and industry to advance the responsible and appropriate use of technology and calls for specific actions from a broad range of invested parties:

- *Everyone:*
  - Understand the role of technology to help improve sleep health, noting its benefits as well as limitations.
  - Adopt consumer technology where appropriate as a tool for measuring, improving, and maintaining sleep, while avoiding overreliance on these functions and interpretation of data.
  - Understand that technology does not replace healthy sleep behaviors, but can support them.
  - Understand users' rights, permissions, and potential uses of personal data when giving consent for access and use by consumer technology companies.
  - Discuss sleep health and goals and any concerns about sleep with healthcare providers.
  - Recognize consumer sleep technology can be a tool to help identify risk for or symptoms of sleep disorders but does not replace a comprehensive evaluation by expert healthcare professionals.
- *Healthcare Providers:*
  - Understand patients' use of consumer technology for sleep and how it might impact clinical interactions.
  - Encourage patients to discuss sleep health and goals when they share experiences with sleep technology.
  - Give patients individualized recommendations about their sleep.
- *Educational and Government Organizations:*
  - Support innovation, safety, and science-backed standardization and evaluation of product claims.
  - Ensure proper measures are taken to protect user data and enforce compliance with privacy regulations.
  - Enact policies that promote scientific and ethical product innovation in consumer technology for sleep.
  - Develop, enact, and maintain data privacy and security standards for the use of consumer technology.
- *Industry:*
  - Ensure scientific rigor in the development, testing, and real-world applications of products for sleep.
  - Support product claims of features, benefits, and technical capabilities using transparent descriptions of methodology and data analysis, while noting limitations.
  - Adopt, adhere to, and promote industry standards and best practices.
  - Take meaningful steps towards broadening accessibility and usability of consumer sleep technology.
  - Use concepts and terms that consumers understand and reflect accepted principles in sleep and health.

    - Support independent rigorous performance evaluation of consumer products consistent with NSF/CTA/ANSI standards for consumer sleep technology (CTA/NSF-2052.3-A; ANSI/CTA-2102).
- *Funding Agencies and Organizations:*
    - Fund independent research, including by nonprofit organizations, to gather and translate insights and raise awareness of the roles of consumer technology in promoting sleep health, wellness, and safety.
    - Support the development, dissemination, and adoption of industry standards and best practices.
    - Foster advances in consumer technology for the identification and/or management of sleep conditions.

Basis for Action: As the public's trusted source for sleep health, the NSF has an essential role as part of its SleepTech® activities to increase consumer knowledge, drive excellence, and promote accountability in consumer technology.

Background: NSF is the leader in efforts to support the public interest through its SleepTech awareness, education, and advocacy programs. NSF considers the category to include a wide array of consumer-facing technology that collects data, offers interpretations of data, or suggests or provides interventions to help monitor or improve a user's sleep. Consumer interest in, access to, and use of these products and services to support health, wellness, and lifestyle is at an all-time high. Consumer technology has been increasingly used for sleep research, clinical diagnostic and treatment aids, and to improve consumer/patient experiences, prompting greater calls for rigorous evaluation. Focus areas related to the use of these products and services include: accessibility, standardization, accuracy, utility, outcomes, security, and privacy.

The US Food and Drug Administration offers guidance on the regulation of medical devices, including software as a medical device. In its policy for low-risk devices, it further defines the scope and conditions for regulatory oversight of general wellness products that can help promote a healthy lifestyle, including giving examples that are related to sleep. Notably, and because there is a wide variety of intended or potential uses for innovative products, it is incumbent on manufacturers to ensure their product claims are appropriate and follow established regulatory guidance and policies. For over a decade, NSF collaborated with the Consumer Technology Association® (CTA) to develop and publish American National Standards Institute (ANSI) certified technology performance and measurement standards for consumer technology products designed for sleep. In addition, NSF acknowledges the intentional and purposeful work of other organizations, including the American Academy of Sleep Medicine, Sleep Research Society, and the World Sleep Society.

Expanding opportunities for sleep health: Technology promises to help increase awareness and understanding of sleep patterns, duration, and disturbances in individuals, families, and communities. Broader access to these solutions may help reduce barriers to achieving healthy sleep and ensure more people have the opportunity to be their Best Slept Self. The NSF leads these efforts through its multiple SleepTech initiatives, including its SleepTech® Network, SleepTech® Award, development of standards and best practices, Sleep in America® Poll and population-based research, all while promoting evidence-based and consensus-driven principles in sleep and circadian health.

Conclusion: Consumer use of technology to support sleep health, wellness, performance, and safety continues to grow. NSF is dedicated to improving health and wellbeing through sleep education and advocacy. NSF's SleepTech advocacy activities and promotion of these consumer products and services have the potential to help advance this mission. It is the position of the National Sleep Foundation that **the appropriate use of science-backed and evidence-based consumer technology products and services for sleep may improve public health and help anyone and everyone be their Best Slept Self®.** NSF has an essential role to maximize the potential benefits of these solutions through its SleepTech programs that increase consumer knowledge, drive excellence, and promote accountability around rapidly evolving consumer technology products for sleep that can improve health and well-being.

Disclaimer: This position statement is not intended to replace guidance for regulated medical devices or devices with certain features and outputs approved/cleared by the US FDA or other global regulatory authorities.