

## APPLE DEBUTS APPLICATION FOR USERS TO PARTICIPATE IN HEALTH STUDIES

Would you share information about your heart rate, menstrual cycle or hearing loss with a technology company? On November 14, 2019, Apple, Inc. ("Apple") launched an application that allows its U.S. customers to enroll in three studies aimed at collecting health-related data that are intended to contribute to medical discoveries called the "Apple Research app." The release of the Apple Research app is one of the most recent examples of how technology companies are entering the health care industry and changing the landscape through devices, data and innovation. While the end result of these moves is still unknown, it is clear that these actions raise significant data privacy and regulatory issues.

### BACKGROUND

In September 2019, Apple announced the upcoming availability of the Apple Research app for Apple products in its App Store. Once downloaded, the Apple Research app determines users' eligibility to participate in three long-term medical studies: (1) the Heart and Movement Study; (2) the Women's Health Study; and (3) the Hearing Study. Each of these studies will be conducted in partnership with government, academic and non-profit entities such as the National Institutes of Health's National Institute of Environmental Health Sciences, Harvard's T.H. Chan School of Public Health and the American Heart Association.

The Heart and Movement Study is expected to last at least five years and will research early warning signs of atrial fibrillation, heart disease and declining mobility. Recently released results from Apple's initial Heart Study, launched in 2017 in partnership with American Well, showed that of the almost 420,000 participants, the Apple Watch detected an irregular heart rate in .52 percent or 2,161 people. Approximately three-quarters of the users who received an irregular pulse notification contacted a health care provider for further treatment, of those, a much smaller percentage were confirmed to have atrial fibrillation following additional testing. This study indicated that wearables like Apple Watches can be potentially useful tools for detecting intermittent conditions such as atrial fibrillation, which have been historically difficult to diagnose using traditional health care procedures.

Apple's Women's Health Study aims to advance knowledge related to menstrual cycles and how they relate to polycystic ovary syndrome, infertility, osteoporosis and menopausal transition.

Apple's Hearing Study seeks to assess how headphone usage and environmental sound exposure can impact a person's ability to hear over time. Data regarding sound exposure will be measured through iPhones and the Noise application on the Apple Watch. The World Health Organization will also receive data from the Hearing Study to raise awareness about safe listening practices.

After enrolling in the Apple Research app, participants can provide data regarding their daily activities, such as their movement, heart rate and noise levels, via their iPhone and/or Apple Watch. Participants will sign consent forms and can choose what types of data they share with each study.

### PRACTICAL TAKEAWAYS

The launch of Apple's Research app is representative of a trend in which companies traditionally focused on technology are making inroads into the health care industry. For example, Google also moved deeper into digital health with its recent \$2.1 billion purchase of Fitbit, a wearable fitness tracker company. In addition, companies like Microsoft, Amazon and Uber are also expanding their presence in the health care space.

The health-related data collected by technology companies may result in promising health care advances, improvements in the diagnosis of certain conditions and increased patient adherence to treatment regimens. However, as technology companies and other non-traditional health care organizations expand their scope to include products and initiatives aimed at collecting health-related data, considerations related to privacy, reliability, reimbursement and other regulatory concerns will arise. The promise of consumer-focused technology can only be accomplished when data is collected in compliance with legal and ethical requirements, and the privacy, security and integrity of the data is assured.

If you have any questions or would like additional information about this topic, please contact:

- **Melissa Markey** at 248-457-7853 or [mmarkey@hallrender.com](mailto:mmarkey@hallrender.com); or
- Your regular Hall Render attorney.

For more information on Hall Render's Health IT services, click [here](#).