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This is an excerpt of *Informed Consent for Research Using Digital Health Technologies: Points to Consider & Sample Language,* developed by NIH.[1] Additional sample language, not reproduced here, deals with the costs of digital health technologies. For a story about the guide, see p. 9. [2]

Introduction

Considerations: The introduction component should provide prospective participants with a description of the digital health technologies used in the study and the purpose of their inclusion. Include a clear statement about how the technology is being used to address the study aims, if the technology has been approved by FDA for its intended use, and if the efficacy of the technology is being studied.

Sample Language:

Instructions: Adjust language as needed. Include "[If the ...]" text if it pertains to your study. Replace embedded instructions identified in *[bold italicized text]* with specific information pertaining to the study. Remember to remove the "[If the ...]" information identified in *[bold italicized text]*.

*The **[insert digital health technology name/type]** will collect **[describe, in plain language, the function of the digital health technology and the types of data it will collect]**. This information will help the study team better understand **[insert general study goal]**.*

[If use of the digital health technology is essential to the study and not optional]:

*As part of this study, you will be asked to use **[insert digital health technology name/type]**. If you do not want to use **[insert digital health technology name/type]**, you should not agree to be in this study.*

***[If one or more digital health technologies used in the study are optional]:** As part of this study, you will be asked to use **[insert digital health technology name/type]**. Use of **[insert digital health technology name/type]** is optional. You can still take part in this study, even if you do not want to use the **[insert digital health technology name/type]**.*

Procedures

Considerations: The procedures component should provide prospective participants with a description of how, when, and under what conditions the digital health technologies will be used in the study.

*Taking part in this study means that you will need to set up **[insert digital health technology name/type]**. This means that you will need to **[describe how the participant must set up, place, install, configure, or activate the digital health technology]**. If you have questions about setting up this device, please contact **[insert contact name, email and/or phone number for study team member that can assist with tech-related questions]**. You will be asked to use **[insert digital health technology name/type]** for about **[insert approximate amount of time (e.g., hours/day)]** over the course of **[specific number of days/weeks/months]**.*

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*You will be asked to share **[insert types of data]** via **[insert digital health technology name/type]** **[insert frequency (e.g., at random intervals throughout the day, daily, weekly)]**. This data will be shared with the study team **[insert frequency with which the data will be shared (e.g., in real-time, every 24 hours, weekly)]**. The **[insert digital health technology name/type]** will continue to collect **[insert types of data]** until the **[insert digital health technology name/type]** is **[insert is removed/uninstalled/or no longer used]**.*

*The data you share with the study team **[will/will not]** be monitored **[if applicable, by whom (e.g., study team, healthcare provider)] [frequency]**. If you have any questions about your health during this study, you should reach out directly to your health care provider(s).*

***[If the digital health technology sends automated notifications and/or computer-generated communications]:** While you are in this study, the **[insert digital health technology name/type]** may send auto-notifications. You should not take these notifications as medical advice. The feedback may not be reviewed by the study team or your healthcare provider(s). If you have concerns about your health while you are in this study, or about the notifications you might be getting, reach out to your healthcare provider(s).*

***[If the study team will be monitoring participant data and sending messages to participants about their health]:** You may receive messages from the study team with information we think you should know about your health. If you have questions or concerns about your health information shared in the message, reach out to **[insert "the study team" OR "your healthcare provider(s)"]**.*

***[If the participant will need to create a user account]:** You will be required to create an account with **[insert digital health technology name/type]** to participate in this study. Creating an account with **[insert digital health technology name/type]** requires providing personal information. If you do not want to do this, you should not agree to be in this study. When you are no longer taking part in the study or choose to stop using the **[insert digital health technology name/type]**, your account will remain open unless you contact **[insert study team or company contact]** to close the account.*

[If one or more digital health technologies has components the user can voluntarily disable]:

***[Insert digital health technology name/type]** has parts that can be turned off by the user including:**([list all components that the user can control])**. You can turn these parts on or off at any given time during the study.*

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