Summary of New NIH Guidance regarding informed consent for research using digital health technologies (May 2024)

I. **Introduction**
   a. In May 2024, the NIH released new guidance on informed consent for research involving digital health technologies (DHT). These are defined as **wearable devices, sensor technologies, and mobile applications**. This guidance aims to enhance transparency and ensure participants understand how their data will be used in such studies. It is recommended researchers read the full document – it contains sample language to use on informed consent documents. Click here to access the full document.

II. **Purpose and data collection**
   a. Researchers must clearly describe the function of the DHT and the types of data it will collect. **This includes whether the use of the DHT is essential or optional for the study.** Provide a description of the DHTs used in the study, and the purpose for their inclusion.

III. **Procedures**
   a. Detailed information on how the DHT will be used including setup instructions, frequency of use, and how it will impact daily activities.
   b. Participants should be informed about the data collection process, data management and sharing practices.
   c. Third-party access: Participants need to know which third parties will have access to their data, the level of access and the frequency of data sharing.

IV. **Sample Language components**
   a. The informed consent should include:
      i. Why the technology is being used to address study aims
      ii. If the technology has been approved by the FDA for its intended use
      iii. If the efficacy of the technology is being studied

V. **Data Sharing and Ownership**
   a. Participants should know if the DHT contains confidential or identifiable information.
   b. Indicate if the data collected is owned by the company and if the data will be sold or shared to third parties without explicit participant consent.
   c. Consider the possibility of re-identification and its implications on participant privacy and confidentiality – how will this risk be mitigated?

VI. **Potential risks, benefits and costs**
   a. **Risks** – risks of continued data collection after study completion, how the study data is being protected, who has access, and the steps being taken to minimize risk.

b. **Potential benefits** – inform prospective participants about any anticipated direct benefits related to their use of digital health technologies during the study.
c. **Costs** – Consent should state who is responsible for which costs related to the digital health technology, whether it's study-provided or a personal device. Include if they need cell service, internet connection, paid access/subscriptions, who will pay for this, and what happens if the DHT breaks or needs maintenance.

VII. Withdrawal

a. Withdrawal should address if the research team or DHT company have access to data after withdrawal or study conclusion.
b. Address if the DHT will continue to collect data until the device or software is removed or uninstalled.
c. Establish and communicate specific criteria and time frames for non-adherence, and ensure ethical considerations are met before formally withdrawing participants who do not request to be withdrawn but show lack of adherence to study activities.