Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Device Software Functions and Mobile Medical Applications

Maricia Dilan, IRB Professional

mdilan@uga.edu

Device Software Functions

- **Device Software Functions:** Software applications that function as a device, which may include:
  - SaMD – Software as a Medical Device
  - SiMD – Software in a Medical Device
- Software functions that meet the definition of a device may be deployed on:
  - Mobile platforms
  - Other general-purpose computing platforms, or
  - In the function or control of a hardware device
- The term “software functions” includes mobile medical applications (apps)

Mobile Apps and Mobile Medical Apps

- **Mobile Platform:**
  - A commercial off-the-shelf computing platform, with or without wireless connectivity, that is handheld in nature such as smartphone, tablet, laptop, or other portable computers

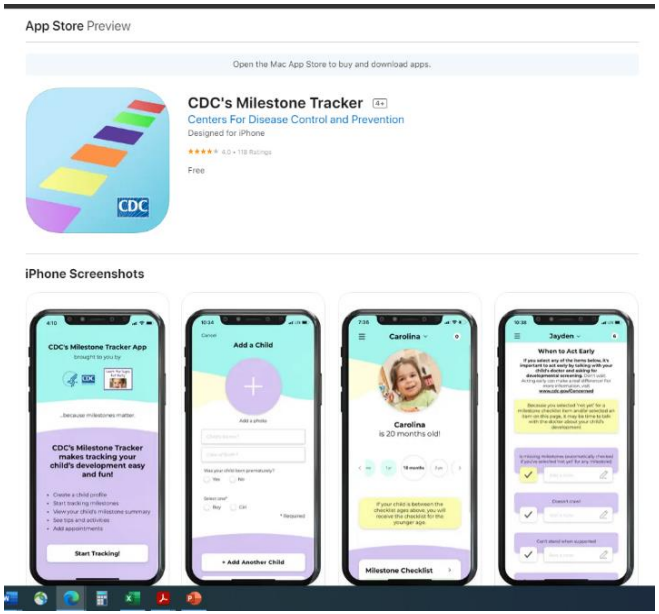
- **Mobile Application (Mobile App)**:
  - A software application that can be executed (run) on a mobile platform or a web-based software application that is tailored to a mobile platform but is executed on a server
  - They can also be accessories that attach to a smartphone or other mobile communication devices, or a combination of accessories and software

- **Mobile Medical Application (Mobile Medical App):**
  - A mobile app that incorporates device software functionality and meets the definition of "device" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and is intended either:
    - to be used as an accessory to a regulated medical device; or
    - to transform a mobile platform into a regulated medical device
  - If a software function that meets the definition of a device is deployed on a mobile platform, it may be referred to as a *mobile medical app*

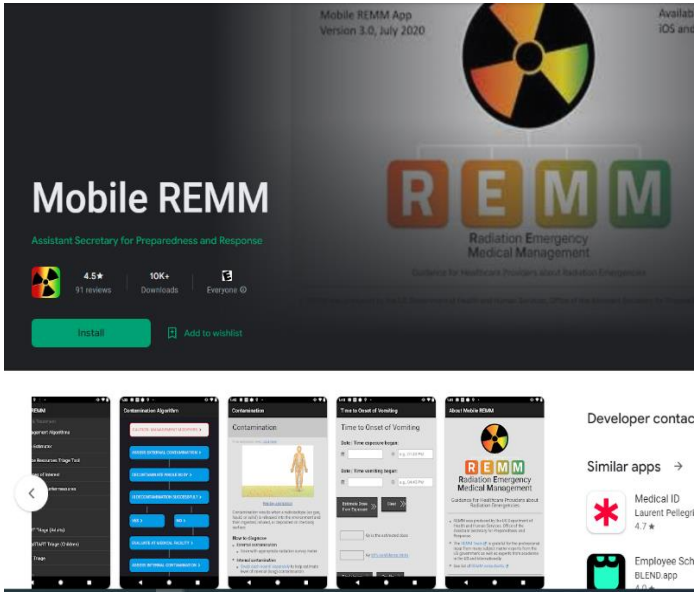
Mobile App & Mobile Medical Apps Examples

Consumer can use both mobile medical apps and mobile apps to manage their own health and wellness

Other apps aim to help health care professionals improve and facilitate patient care



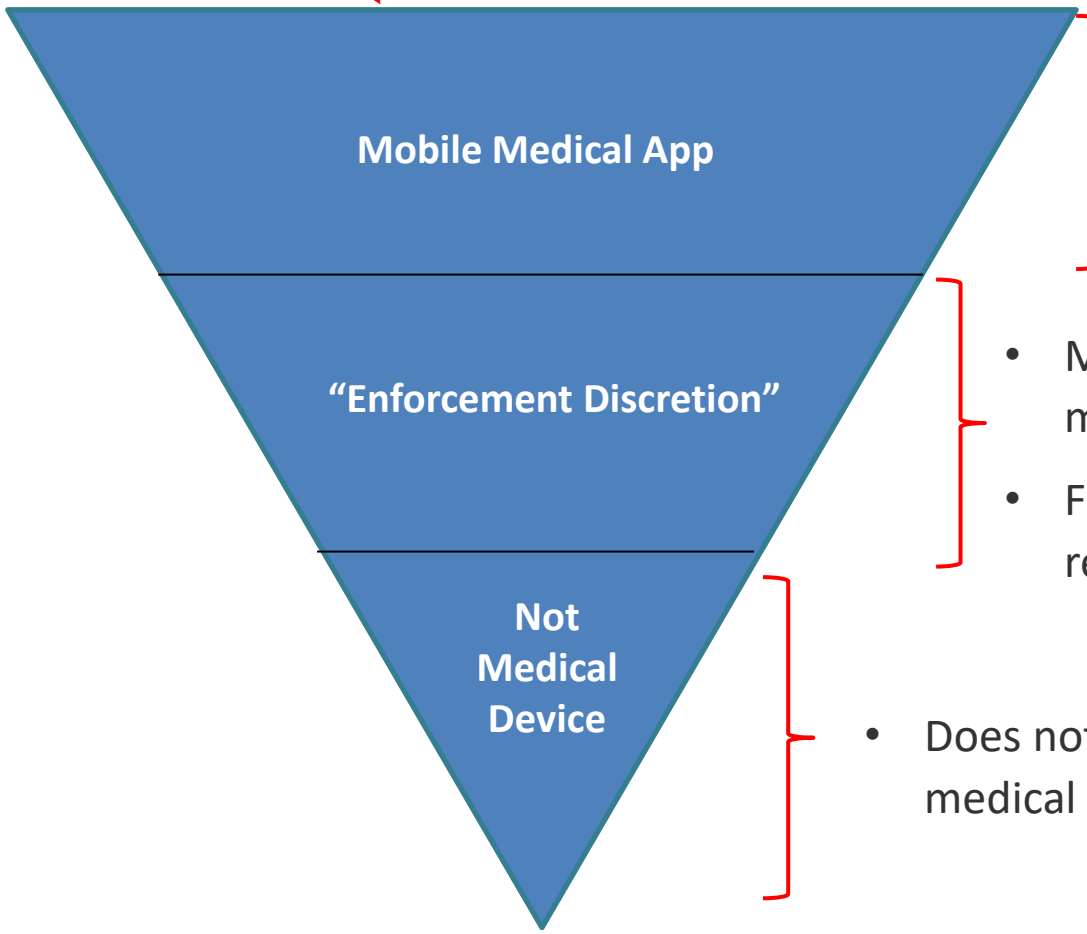
Provides checklists for parents and caretakers to see if an infant or child is meeting common developmental milestones.



Gives health care providers guidance in diagnosing and treating radiation injuries

Software Functions Categories

Focus of FDA's Regulatory Oversight



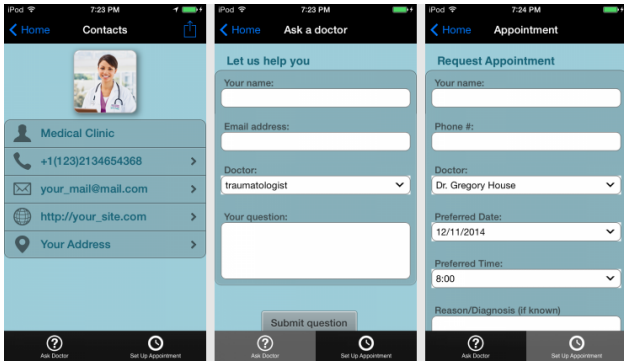
- Meets the definition of medical device and are higher risk

- May meet the definition of medical device but are lower risk
- FDA does not intend to enforce requirements under the FD&C Act

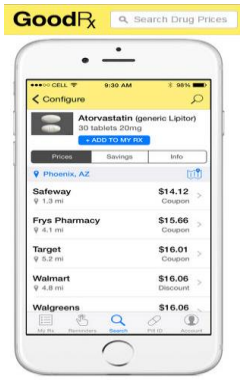
- Does not meet the definition of medical device

Examples of Software Functions that are NOT Medical Device

E-Books/Audio Books of Medical textbooks



Office automation (e.g., Manage doctor's appointment)



Patient reference info (useful links, compare drug costs)

Interactive diagrams; medical training videos

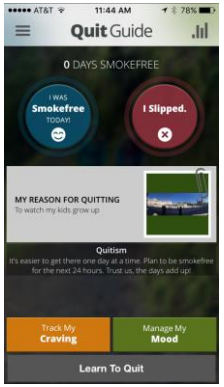
General purpose (e.g., note-taking, audio recording)

NOTE: It should not be intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease

Examples of Software Functions - “Enforcement Discretion”

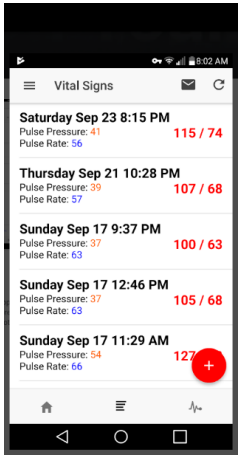
Helps patients with psychiatric conditions maintain their behavior

Uses video or video games to motivate patients to do physical therapy exercise at home



Provides motivational guidance, reminders (people trying to quit smoking, recovering from addiction, pregnant)

Uses GPS location info to alert asthmatic of environmental conditions that may cause asthma (or addiction patient when near a pre-identified high-risk location)



Provides historical trending and comparison of vital signs (e.g., body temperature, heart rate, blood pressure, or respiratory rate)

Medical Alert System - Enables a patient or caregiver to create and send an alert or general emergency notification to first responders

Software Functions that are subject to FDA's Regulatory Oversight

- FDA intends to apply its regulatory oversight to device software functions that meet the definition of medical device and that:
  - Presents greatest risk to patients if the device were not to function as intended and
  - Causes smartphones (or other mobile platforms) to impact the functionality or performance of traditional medical devices

Software Functions/Mobile Apps that meet the definition of medical device and can pose potential risk to public health

1. Extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or analyzing medical device data.

2. Transforms the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.

3. Becomes a regulated medical device (software) by performing patient-specific analysis and providing specific output(s) or directive(s) to health care professionals for use in the diagnosis, treatment, mitigation, cure, or prevention of a disease or condition.

   - Additionally, those that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations to patients, caregivers, or other users who are not health care professionals.

Examples of Software Functions that are Focus of FDA's Regulatory Oversight

A. Software functions (typically mobile apps) that transform a mobile platform into a regulated medical device:

Uses a sensor that is connected to a mobile platform to measure and display the electrical signal produced by the heart (ECG)

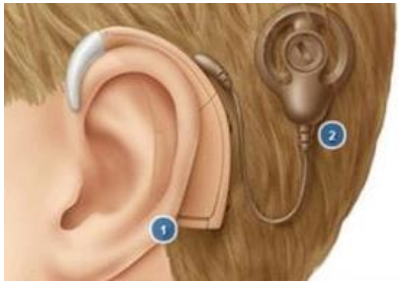
Uses an attachment to the mobile platform to measure blood glucose levels

Uses an attachment to the mobile platform (e.g., light source, laser) to treat acne, reduce wrinkles, or remove hair

Examples of Software Functions that are Focus of FDA's Regulatory Oversight (cont.)

B. Software functions that connect to an existing device type for purposes of controlling its operation, function, or energy source:

Alters the function or settings of an infusion pump



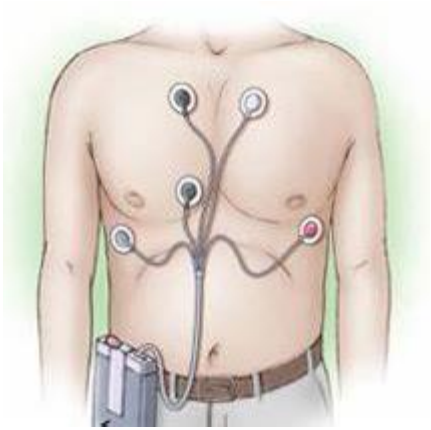
Calibrates, controls, or changes settings of a cochlear implant

Controls the inflation or deflation of a blood-pressure cuff

Examples of Software Functions that are Focus of FDA's Regulatory Oversight (cont.)

C. Software functions that are used in active patient monitoring or to analyze patient-specific medical device data:

Processes uterine contraction and fetal heart rate data for remote monitoring of labor progress



Intended for health care professional management of heart failure patients that analyzes patient-specific medical information (e.g., daily heart rate, SpO2, blood pressure, or other output from wearable product) to predict heart failure hospitalization

Acquires or processes physiological signals that connect to bedside (or cardiac) monitors for active patient monitoring

Use of Device Software Functions/Mobile Medical Apps in Research

- As an Investigational Device – to evaluate its safety and/or effectiveness (21 CFR 812)
  - PI (Sponsor) will initially determine if the device is Significant Risk (SR) or Non-Significant Risk (NSR) and follow FDA and IRB processes accordingly
- As a Data Collection Tool, SR and NSR determination is not required
  - IRB will review the informed consent process, study procedures, confidentiality, privacy, and data security related to the use of the device software functions or mobile medical apps

Study Procedures: What will the IRB review?

Aside from the other study procedures, the following should be reviewed:

1. The name of the app and explanation whether it is commercially available or being developed for the current study

2. Description on how the participant is accessing the app or software
   - e.g., are participants using their own device (*e.g.,* phone, tablet, computer or does the study team provide it?) If the study provides the device, description on what happens to the device when the study is complete

3. A detailed information about what the app does, how the participant interacts with the app, and the app's role in the study
   - e.g., brochure, product link to the store manufacturer

4. Include the name and institutional affiliation of the app developer. (**Note:** If it is a non-UGA developer, contact HSO as a Data Use Agreement or contract may be required)

Confidentiality and Privacy: What will the IRB review?

Aside from the other risks associated with the study, the following should be reviewed:

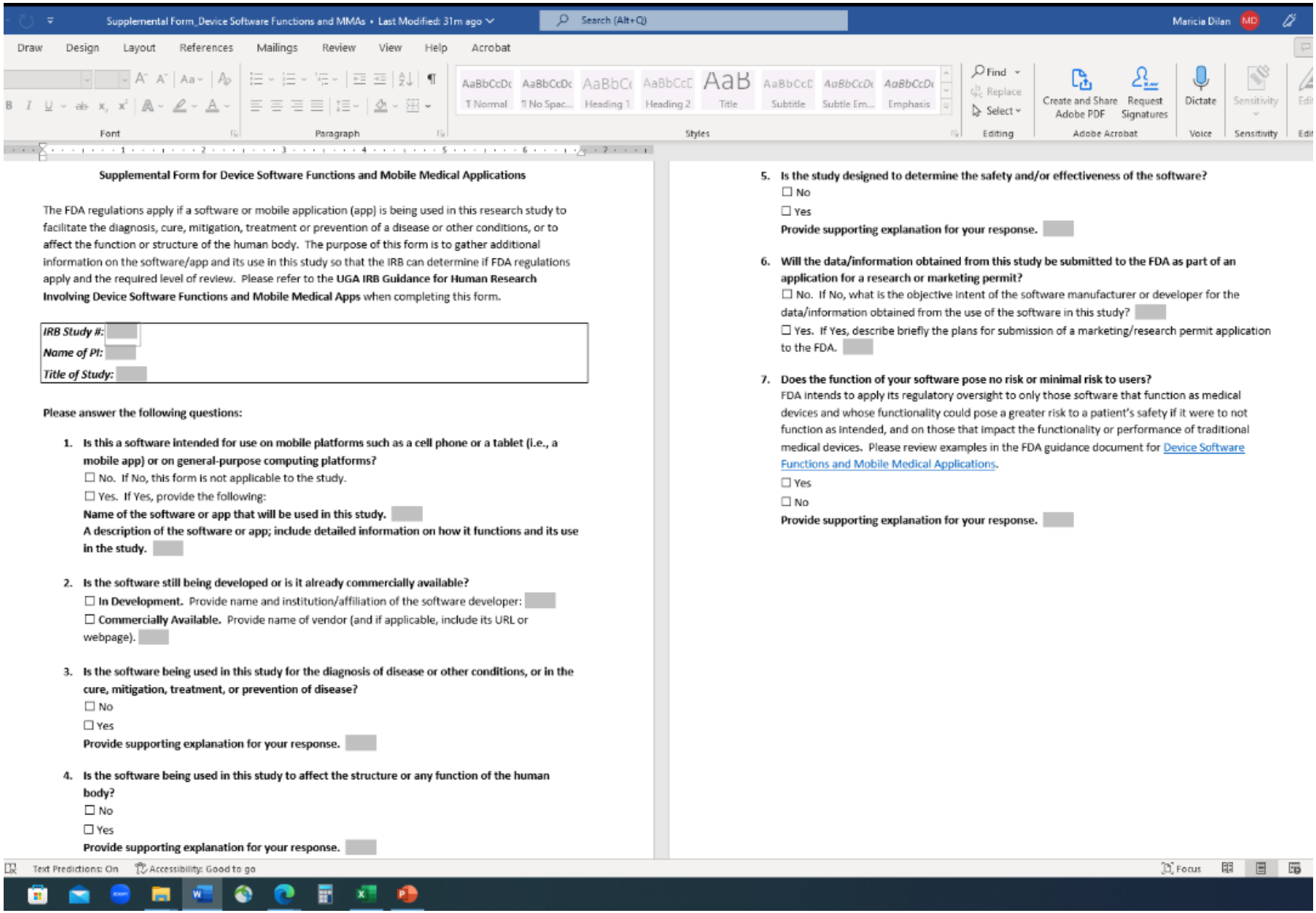
1. Potential Breaches in Confidentiality
2. Risk of a 3rd Party
   - E.g., app makers, other installed apps, other device users, any other outside actors
3. Data usage plan, if applicable
4. Risk if app does not work as intended
   - E.g., If the app is designed to transmit important vitals or labs but does not function as intended, or if the app fails to accept participant input or transmit as intended. Describe what participants are expected to do and any risks associated with this type of system malfunction.

Informed Consent: What will the IRB review?

Aside from the required elements of consent, the following should be reviewed:

1. Enough detail of the software/mobile app, research procedures, and the potential risks
2. An explanation if participants will use their own device to download the app or will be loaned by researchers
3. If will be loaned, description of logistics for returning the device and what to do if device is not working properly
4. Language about agreeing to Terms of Use on the data collection and sharing of data to 3rd party
5. Explanation on how confidentiality and privacy will be maintained
6. Explanation of data usage fee, if applicable

Supplemental Form for Device Software Functions and Mobile Medical Applications



Supplemental Form for Device Software Functions and Mobile Medical Applications

The FDA regulations apply if a software or mobile application (app) is being used in this research study to facilitate the diagnosis, cure, mitigation, treatment or prevention of a disease or other conditions, or to affect the function or structure of the human body. The purpose of this form is to gather additional information on the software/app and its use in this study so that the IRB can determine if FDA regulations apply and the required level of review. Please refer to the **UGA IRB Guidance for Human Research Involving Device Software Functions and Mobile Medical Apps** when completing this form.

IRB Study #:
Name of PI:
Title of Study:

Please answer the following questions:

1. **Is this a software intended for use on mobile platforms such as a cell phone or a tablet (i.e., a mobile app) or on general-purpose computing platforms?**
   - ☐ No. If No, this form is not applicable to the study.
   - ☐ Yes. If Yes, provide the following:

   Name of the software or app that will be used in this study.
   A description of the software or app; include detailed information on how it functions and its use in the study.

2. **Is the software still being developed or is it already commercially available?**
   - ☐ **In Development.** Provide name and institution/affiliation of the software developer:
   - ☐ **Commercially Available.** Provide name of vendor (and if applicable, include its URL or webpage).

3. **Is the software being used in this study for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease?**
   - ☐ No
   - ☐ Yes

   Provide supporting explanation for your response.

4. **Is the software being used in this study to affect the structure or any function of the human body?**
   - ☐ No
   - ☐ Yes

   Provide supporting explanation for your response.

5. **Is the study designed to determine the safety and/or effectiveness of the software?**
   - ☐ No
   - ☐ Yes

   Provide supporting explanation for your response.

6. **Will the data/information obtained from this study be submitted to the FDA as part of an application for a research or marketing permit?**
   - ☐ No. If No, what is the objective intent of the software manufacturer or developer for the data/information obtained from the use of the software in this study?
   - ☐ Yes. If Yes, describe briefly the plans for submission of a marketing/research permit application to the FDA.

7. **Does the function of your software pose no risk or minimal risk to users?**
   FDA intends to apply its regulatory oversight to only those software that function as medical devices and whose functionality could pose a greater risk to a patient's safety if it were to not function as intended, and on those that impact the functionality or performance of traditional medical devices. Please review examples in the FDA guidance document for Device Software Functions and Mobile Medical Applications.
   - ☐ Yes
   - ☐ No

   Provide supporting explanation for your response.

Helpful Links

- FDA: Medical Devices (21 CFR Subchapter H, Part 800-898)
- FDA: CDHR Learn
- Device Advice: Comprehensive Regulatory Assistance | FDA
- FDA: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors
- UGA Guidance on FDA-Regulated Research
- UGA Checklist 418 – Non-Significant Risk Device; Worksheet 307 – Devices
- UGA Supplemental Form_Device Software Functions and MMAs
- UGA Guidance for Human Research Involving Device Software Functions and Mobile Medical Apps

Thank you!