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| --- | --- |
|  | **INVESTIGATOR CHECKLIST FOR****Studies Using Mobile Apps** |
| The purpose of this checklist is to help investigators and the IRB determine whether a mobile app constitutes a ***mobile medical app***. If a mobile app is considered a mobile medical app, you also need to complete the [Emory IRB Device Checklist](http://irb.emory.edu/documents/Emory_IRB_Checklist-IDE_Exempt-NSRD-SRD.docx).A mobile application or “mobile app” is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server. Per the FDA, “a ‘mobile **medical** app’ is a mobile app that meets the [definition of device](https://www.fda.gov/aboutfda/transparency/basics/ucm211822.htm) in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either is intended: * To be used as an accessory to a regulated medical device; or
* To transform a mobile platform into a regulated medical device.

Thus, the FDA mobile medical device regulations apply to you if you are using a mobile application in a research study, and that app is being used to facilitate the diagnosis, or mitigation, of a disease, or to affect the function or structure of the human body. The purpose of this worksheet is to establish and document what level of review your app requires. |
| IRB number:       | Study Title:       |
| PI Name:       | Person completing this form:        |
| **Instructions**: Please answer the following questions |
| 1. **Is this a mobile app., i.e. a software application that can (but is not necessarily) run on a mobile platform. It can also include web-based software applications executed on a server?**
 |
| [ ]  No. If no, stop as this worksheet is not applicable to the study. Please contact your analyst if you have any questions. |
| [ ]  Yes. If yes, provide the app/software name and brief description, and how it will be used in the study:       |
| 1. **Does the proposed mobile app involve the collection or storing of PHI?**
 |
| [ ]  Yes. If yes, submit an IT ticket through the following link: <https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2> (please, copy a paste link in a browser). |
| [ ]  No. If no, the mobile app does not need to be vetted by LITS. |
| 1. ***If the answer to any of the following questions is “yes”, your device is NOT a mobile medical app or is an app under FDA enforcement discretion. You do NOT need to fill out the “Devices” section in the eIRB submission. Attach this completed form under “Local Site Documents” and skip to Section E.***
 |
| **Is this a mobile app that solely performs simple calculations routinely used in clinical practice? See examples** [**in this FDA policy**](https://www.fda.gov/media/80958/download) **(**Policy for Device Software Functions and Mobile Medical Applications) |
| [ ]  Yes | [ ]  No |
| **Is this a Mobile app that is specifically marketed to help patients document, show, or communicate to providers potential medical conditions? See examples** [**in this FDA policy**](https://www.fda.gov/media/80958/download) **(**Policy for Device Software Functions and Mobile Medical Applications) |
| [ ]  Yes | [ ]  No |
| **Does this mobile app solely enable individuals to interact with PHR systems or EHR systems? See examples** [**in this FDA policy**](https://www.fda.gov/media/80958/download) **(**Policy for Device Software Functions and Mobile Medical Applications) |
| [ ]  Yes | [ ]  No |
| **Does this mobile app meet the definition of Medical Device Data System? See examples** [**in this FDA policy**](https://www.fda.gov/media/88572/download) **(**Policy for Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communication Devices) |
| [ ]  Yes | [ ]  No |
| **Is this a Mobile app that solely provides patients only with simple tools to organize and track their health Information?**  |
| [ ]  Yes | [ ]  No |
| **Does this app solely provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment? See examples** [**in this FDA policy**](https://www.fda.gov/media/80958/download) **(**Policy for Device Software Functions and Mobile Medical Applications) |
| [ ]  Yes | [ ]  No |
| 1. ***If the answer to any of the following questions is “yes”, your device is considered a mobile medical app. Complete the*** [***Emory IRB Device Checklist***](http://irb.emory.edu/documents/Emory_IRB_Checklist-IDE_Exempt-NSRD-SRD.docx)***, complete the “Devices” section in the eIRB application, and attach both checklists in that section. Proceed to Section E.***
 |
| **Is the Mobile app used as an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device? See examples** [**in this FDA policy**](https://www.fda.gov/media/80958/download)(Policy for Device Software Functions and Mobile Medical Applications) |
| [ ]  Yes | [ ]  No |
| **Is the intention of this app to transform 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? See examples** [**in this FDA policy**](https://www.fda.gov/media/80958/download) **(**Policy for Device Software Functions and Mobile Medical Applications) |
| [ ]  Yes | [ ]  No |

1. **Additional requirements for the Informed Consent Form and Protocol:**
2. **Will the Mobile app be installed on the subjects’ mobile device?**

[ ] No

[ ] Yes.

 If yes, please address the following questions in the protocol and the informed consent form:

* + Will the information input into the app be encrypted?
	+ Will the study team be able to monitor the activity of the mobile device? If so, how will it be done?
	+ What are the security measures being taken to ensure the confidentiality of their information?
	+ How will the app be removed from their device?
		- The removal of an app from a subject’s device should be included and detailed in the “exit” procedures associated with a subject’s completion of the study.
1. **Will the subject be provided a mobile device on which to use the app?**

[ ]  No

[ ]  Yes.

If yes, please include the following questions in the protocol and the informed consent form:

* + Who is responsible for payment of the phone?
	+ Who is responsible for the fees (e.g.: data, phone calls, texting fees)?
	+ If the device is being “overused” (beyond what was assumed to be need for purposes of the study) who pays for the additional fees?
	+ What happens if the phone is broken, stolen or lost?
	+ Is there a security measure put in place to deactivate or wipe the mobile phone in the event that it was lost or stolen? If so, what are they?
	+ Can the subject keep the phone upon completion of the study, or must it be returned?