Please use this submission form for research studies involving the use of a “mobile app.” A “mobile app” is defined as a software application that can be 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.

Submission of this form is required when the app:

* is the sole focus of the research (e.g., research on an app that controls the delivery of insulin through an insulin pump)
* is used as a tool in collecting data for the research (e.g., app that collects patient recorded outcomes through surveys)
* provides logistical support (e.g., app that sends reminders to take a study drug).

Please include the following in your protocol submission:

1. Screen shots from the app
2. License agreement, terms of use, privacy policy, or any other document that participants are presented with or must agree to in order to use the app (if applicable)
3. eConsent submission form (if applicable)

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| Please ensure that the information provided below is included in the protocol and/or consent form, as appropriate. |
| **SECTION 1.0: Use of the Mobile App** |
| 1. Overview of mobile app: 2. Name of app: 3. Briefly describe what the app is designed to do:   c. Select one: Commercial (“off the shelf”) app Custom-built app created for this research study  d. Select one or both: Researcher-facing app  Participant-facing app  e. Select one or more of the following to describe the use of the app in the research:  The research is being conducted to determine the validity of the app (e.g., app controls the delivery of insulin through an insulin pump)  The app will collect, store, or transmit participant data (e.g., app collects patient recorded outcomes through surveys)  The app is being used to provide logistical support but does not collect, store, or transmit participant data (e.g., app sends reminders to take a study drug)  Other: |
| 1. Is participant use of the app in the research mandatory or optional?   N/A – app is researcher-facing only  Mandatory  Optional. Please explain why it is not mandatory and what alternatives there are (e.g., phone call reminders to participants instead of app reminders):  Please ensure that participants are informed of alternatives, as appropriate, via the consent form. |
| 1. What are the risks of the app not working as intended, and what mechanisms are in place to minimize these risks (e.g., monitoring of the app, alerts to researchers/participants)?   Please ensure that the consent form describes these risks as appropriate. |
| 1. Describe any support that is available for technical questions about the app, at study start and then ongoing: |
| 1. Will mobile device (e.g., phone, tablet) be provided to participants or will they be required to use their own devices?   N/A – app is researcher-facing only  Participants will be required to use their own devices  Devices will be provided to participants  Please ensure that the consent form includes this information, as well as the process for device return or replacement if applicable. |
| 1. Will participants be required to pay for use of the app (for instance, at initial download or as a subscription)?   N/A – app is researcher-facing only  No  Yes. Please describe what payment will be required and whether participants will be reimbursed. Please ensure that this information is included in the consent form. |
| |  | | --- | | 1. Is there a license agreement, terms of use, privacy policy, or any other document that participants are presented with or must agree to in order to use the app?   N/A – app is researcher-facing only  No  Yes  If yes, please submit it for review and check the boxes to confirm that the following is done:   1. The consent form must state that participants will be asked to agree to the terms of the document and that they can say no but then would not be able to use the app (if use of the app is optional) or would not be able to participate in the research (if use of the app is required). 2. Information included in the document regarding privacy, data use, risks associated with the app, and any other information that may affect a potential participant’s decision of whether to participate is also briefly described in the consent form. 3. The document does not include potentially exculpatory language (language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt***). If the document does include such language and it is possible to remove it, please do so prior to submission***. Otherwise, the consent form must include a statement notifying participants that, regardless of the language in the document, they do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the app in the research study.   Document does not include potentially exculpatory language Statement added to consent form  If any of the above boxes are not checked, please explain:  **Template consent form language:**  *The following template language may be adapted and inserted into the consent form in order to satisfy the requirements outlined above.*    Blue = instructions for person drafting consent form language  Red = text to choose from/that needs to be revised  ***Use of the XYZ Mobile App***  As part of this research study you will [need to OR have the option] to use the XYZ app. In order to use the app you will be asked to agree to the [name of document: Terms of Use/Privacy Policy] which will appear on your mobile device’s screen when you first start using the app. [Select one: If you decide that you do not want to agree, then you should not participate in the research. OR If you decide you do not want to agree, then you can chose not to use the app and still participate in the research.]  Insert if the agreement includes data sharing and privacy information not already included in the ICF: While using the app, data about you including [list specific information, such as: personal health information, location, other communication data, and internet usage] will be collected and transmitted [to the researchers AND/OR to people outside of the research study].  A complete description of this data collection and sharing is found in the [name of document: Terms of Use/Privacy Policy]. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information. [If applicable: The [name of document: Terms of Use/Privacy Policy] provides instructions on how to request deletion of your personal data if you decide to do that in the future.]  Insert if the agreement includes exculpatory language: While the [name of document: Terms of Use/Privacy Policy] may include statements limiting your rights if you are injured in this study, you do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the XYZ app in this research study.  Insert additional information as needed here: | |

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| **SECTION 2.0: Data Security**  *Please complete this section if the research if the app will collect, store, or transmit any participant data*   |  | | --- | | 1. If the research is stopped for an individual participant or the study, please describe how the app will be suspended remotely and/or how participants will be notified.   N/A – app is researcher-facing only | | 1. If a participant decides to withdraw from the study, please describe how they will be able to deactivate the app. Please ensure this is described in the consent form.   N/A – app is researcher-facing only | |
| |  | | --- | | 1. Is any participant data collected, stored, or transmitted identifiable?   No  Yes. Please describe what data will be collected and who will have access to it (including any third parties), and ensure this is included in the consent form. | | 1. Does the app capture incidental data about the participant (e.g., location stamps)?   No  Yes. Please describe what data will be collected and who will have access to it (including any third parties), and ensure this is included in the consent form. | | 1. Describe potential risks to confidentiality and data security and what mechanisms are in place to minimize these risks (e.g., passwords, biometric authentication, secure transport, data encryption): | |

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| **SECTION 3.0: Quality Testing**  *Please complete this section if the app is custom-built for use in this research study* |
| 1. Has the app undergone quality assurance testing for functionality, compatibility, performance, stability, and security?   Yes  No. Please explain: |

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| **SECTION 4.0: Device information** |
| FDA regulates a subset of mobile apps which meet the definition of “mobile medical app.” A “mobile medical app” is a mobile app that meets the statutory definition of a device and either is intended (1) to be used as an accessory to a regulated medical device, or (2) to transform a mobile platform into a regulated medical device.  Detailed FDA guidance on mobile medical applications is available [**here**](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf).  Sponsors are responsible for determining whether an Investigational Device Exemption (IDE) application is required for the proposed research. Please select one of the following and submit supplemental documentation supporting your determination:   1. Does the mobile app meet the definition of an investigational device? No  Yes   If yes, select one of the following and attach the applicable documentation:  FDA letter granting an Investigational Device Exemption (IDE) for the proposed use;  Letter from the Sponsor stating that the app is a non-significant risk device; or  \*Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c).  \*This letter must be provided for the study to qualify for expedited review (MRR).  Comments: |