## Primary Reviewer(s):

## Review Date:

## Project / Protocol Title:

*Use this form to supplement the Protocol Evaluation Form for all mobile apps*

All digital content that will be viewed by subjects should be reviewed. This includes license agreements, privacy policies, and any other documents that participants are presented with or must agree to in order to use the app.

1. Confirm the following:

*The accessibility and usability of the app is appropriate given the user population and complexity of activities to be performed via the app.*

*The consent form states whether participant use of the app is mandatory or optional.*

*N/A – app is researcher-facing only*

*If the app is optional for participants, there are alternatives to using it if appropriate and they are described in the consent form.*

*N/A – app is mandatory for participants*

*N/A – app is researcher-facing only*

*There are mechanisms in place to minimize the risks of the app not working (e.g., monitoring of the app, alerts to researchers/participants, technical support, etc.).*

*N/A – none needed because (e.g., research is minimal risk and no mechanisms are needed to minimize risk):*

*Consent form states whether participants will be required to use their own devices or whether devices will be provided to them. If devices are provided, the consent form describes the process for device return or replacement.*

*N/A – app is researcher-facing only*

*If participants will be required to pay for use of the app, the cost is reasonable and details (including reimbursement, if applicable) are included in the consent form.*

*N/A – participants are not required to pay*

*N/A – app is researcher-facing only*

*If the app is custom-made, it has undergone quality assurance testing for functionality, compatibility, performance, stability, and security.*

*N/A – app is not custom-made*

*Participant termination and withdrawal procedures involving the app are appropriate for the study and described in the consent form if needed.*

*N/A – app is researcher-facing only*

*If there is 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 – no agreement/document for participant to use the app*

*N/A – app is researcher-facing only*

*OR*

*Consent form includes statement that participants will be asked to agree to the terms and can say no, and states the impact of saying no; and*

*Consent form includes basic information 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; and*

*Either the document does not include potentially exculpatory language, or the consent form includes a statement explicitly 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.*

*(\*If revisions are required to the document to remove exculpatory language, or additional language preserving participants’ rights must be added to the consent form, please note this below.)*

*Consent form describes what, if any, data will be collected, stored, or transmitted via the app (including both research data and incidental data) whether it is identifiable, and who will have access to it.*

*There are mechanisms in place to minimize potential risks to confidentiality and data security (e.g., passwords, biometric authentication, secure transport, data encryption).*

*N/A – none needed because (e.g., no participant data is collected, stored, or transmitted via the app):*

3. Reviewer Comments