A Pilot Study of the Womb Watch App: Fetal Assessment Using the Microphone of the Smartphone

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IRB TEMPLATE: Standard Protocol Form	
NUMBER	VERSION DATE
HRP-UT901	1/27/2026

About this Form

This form is required for research studies that are greater than minimal risk, or minimal risk qualifying for expedited review. You can also use this form if you are unsure which review level and/or form is best.

Additional forms/tools are available for the following:

- Requesting a "Not Human Subjects Research" (NHSR) determination
- Exempt Research requiring only institutional review
- Secondary Use Research where there is no contact with participants
- Non-research treatment protocols (HUDs, EAPs/Compassionate Use, Emergency Use)

Need help deciding which form to use? Refer to our IRB Template Decision Tree. All protocol templates are available in the UTRMS-IRB Library.

For studies following a sponsor protocol, please use this guidance to assist in your completion of this form.

Be aware that other institutional requirements outside the scope of IRB review may apply to your research. Please see the UT Austin Human Research Navigation Tool for guidance on additional requirements that may apply.

Instructions for Use

Do not convert this Word document to PDF. PDFs block certain review functionality in UTRMS-IRB (such as the ability for staff to see system-tracked changes when edits are made) which can hinder review.

This form uses skip logic. Complete the form in order and answer all questions unless instructed to skip via *special instructions* based on previous responses.

To fill in a text box, make sure your cursor is within the *grey text box* before typing or pasting text. Boxes will expand to accommodate the full length of text added.

Once complete, upload this form on the Basic Study Information section of the online application where prompted to upload the protocol (typically question 7 or 8 depending on previous responses).

Please do not delete the Index.

Index

General Study Information	Consent/Assent Pathways	Risks & Discomforts
Study Elements w/ Add'l Requirements	Add'l Consent Considerations/Disclosures	Privacy & Confidentiality
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Recruitment & Screening	Benefits	Conflicts of Interest

General Study Information

Study Title:

A Pilot Study of the Womb Watch App: Fetal Assessment Using the Microphone of the Smartphone

1. Review Type (Choose one)

Please choose which level of review best fits your research. This is an investigator's assessment of review and does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination of review conflict, the IRB's determination will be considered the official determination.

Note: "Expedited" review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by OHRP. If you would like help determining which type of review best fits your research study, please contact the IRB staff in the Office of Research Support & Compliance: https://research.utexas.edu/ors/human-subjects/get-help/

Click on the appropriate check box (or double click and type an "X" if using Google Docs):

☐ Full Committee – Greater than Minimal Risk Research

☒ Single Reviewer – Minimal Risk Research (expedited)

1a. Notification of UT IRB Fees

Be aware that the UT IRB may charge fees for certain types of reviews. If your project qualifies for either of the project types listed below, check the appropriate box and review our website for more information about IRB fees that may apply. Please reach out to irb@austin.utexas.edu if you have questions.

☐ Industry-sponsored Clinical Trial → *If checked, select one of the following, as applicable:*

- ☐ UT Austin/Dell Medical School holds the contract
- ☐ Ascension holds the contract

☐ Federally-Funded multisite study for which UT IRB is serving as the single IRB of record *(for guidance, see our website for Single IRB Reliance)*

2. External Time Limitation

Generally, the IRB will review applications in the order in which they are received. When possible, the IRB can assign higher priority to research with externally-imposed urgency that is beyond the control of the researcher (example: grant deadlines, research responding to a sudden or emerging event, etc.).

Completing this section provides the IRB with information but does not guarantee priority review is possible or that a requested deadline can be met. Researchers are encouraged to communicate with the IRB as soon as possible when there is an urgent situation (ideally before submitting the IRB application), and we will do our best to accommodate requests, as possible: https://research.utexas.edu/ors/human-subjects/get-help/

Are you requesting the IRB consider priority review due to an *externally-imposed* deadline or time limitation affecting this submission?

☐ No

☒ Yes → *If yes, briefly describe the urgency or deadline below, including the reason for it:*

Working within confines of budget timeline provided by UT REAL AI Pilot Program Grant

3. Is the research taking place at or using data from any of the following:

Knowing when UT's external clinical partners are involved helps inform IRB review and reporting.

☐ None of these

☐ Health Discovery Labs

☐ Central Health

☐ CommUnity Care

☒ Ascension locations → *Submit a request to the Seton Site Approval Tool (SAT) and upload the confirmation email that states the request has been submitted in UTRMS under "Other Documents." Please note, we do NOT need the final approval letter (you will not receive SAT approval until after IRB approval is granted). If you encounter issues or have questions about SAT, please reach out to siteapproval@seton.org.*

4. Research Hypotheses

Please describe the research aims and hypotheses in the box below. Note: Procedures will be explained in a separate section below.

This study explores the real-world feasibility of a low-cost approach using smartphone audio recordings and Artificial Intelligence (AI) to provide objective, reliable fetal assessment metrics via the Womb Watch smartphone application.

5. Study Background

Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

The surveillance of pregnancies at risk for fetal loss secondary to high-risk maternal or fetal conditions remains a mainstay of perinatal care. Current testing to prevent fetal loss includes the regular use of ultrasound (biophysical profile) or fetal heart rate monitoring (non-stress test) in an outpatient clinic setting once or twice weekly. A patient may also be asked to subjectively assess daily fetal movements during the time between routine antepartum testing appointments. However, there are no good systems for pregnant women to objectively measure fetal movements. Smartphones have allowed for the development of applications that utilize various embedded devices including the camera and microphone. In our recent pilot STUDY00001552 of 200 pregnant patients, placement of the iPhone10 microphone directly on the maternal abdominal wall was utilized to detect fetal movements. AI assessment of the audio recordings proved superior to maternal perception of fetal movements that were recorded during simultaneous ultrasound (gross fetal movements: 64% audio vs 18% maternal; breathing: 93% vs 3%, hiccups: 73% vs 3%).

This is a prospective, observational, feasibility study of 75 patients that includes both low-risk and high-risk pregnant women to examine the usability of the Womb Watch smartphone application.

The study will involve introduction of the Womb Watch app to a population of pregnant patients. Features of the app will be modified based on participant feedback, periodic assessment of anxiety levels during use of the app, and assessment of the participant's perceived strength of fetal movements. The participants' personal profile (called Trends within the app) will include an assessment of fetal movements, fetal breathing, fetal hiccups and their intensity of movements score. This data will not be included in the participant's EMR.

6. Design and Methodology

Provide a brief description of the overall study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in the next section below.

This is a prospective, observational, feasibility study in which pregnant women between 28 – 40 weeks gestation will record sounds coming from their pregnant abdomen daily for 15 minutes with the Womb Watch smartphone application. Audio signals will be registered by the participant using the microphone of the smartphone held vertically against the pregnant uterus. In addition, the gyroscope and accelerometer sensor data will be captured for assessment of maternal abdominal wall movement. The gyroscope measures angular velocity and the accelerometer measures acceleration, motion, tilt and vibration. This is to assess gross motor movements of the fetus, such as a kick. The audio, gyroscope and accelerometer files will be uploaded from the Womb Watch app via Google Firestore to an encrypted database at the Texas Advanced Computing Center (TACC-UT Austin). The model is investigator-developed by Co-I, Dr. Kelly Gaither and internally hosted by UT TACC. A deep learning/machine learning model will be employed to determine the number of three categories of fetal movements based on these files: gross body movements, fetal breathing and fetal hiccups. The participants will be asked to assess the strength of fetal movements after each recording session using a Likert scale in the app. After 5-10 minutes from sending the files to TACC, participants will be notified via email that the deep/machine learning analysis regarding these movements is available to view on the customized app. Analysis is based on the deep learning/machine learning model assessment. The uploaded files are used to train and refine the model. Amniotic fluid levels, based on routine clinical ultrasounds, will also be incorporated into the model to assess their effect on audio signals. No other data sets are used to refine the deep learning/machine learning model.

The app will be dynamic in that changes based on patient input to further enhance the useability will be incorporated into new versions. In addition, the app will be adaptive in using deep learning to improve the interpretation of the audio recordings. As new versions of the app are developed, they will be pushed to all participants' smartphones that are actively involved in the study.

Baseline and periodic determinations of participant anxiety will be undertaken using the GAD-7 survey tool (7 questions with 4 levels of response for each question) every 4 weeks through an online REDCap link provided to participants via their personal email.

7. Study Procedure Description

Provide a step-by-step narrative of what enrolled participants will be asked to do or allow, and/or how data/specimens will be collected and used, such that someone else could replicate the procedures based on this description.

Recruitment and consent procedures will be covered in later sections. The description below should cover all procedures involving enrolled subjects or participants (or their data/specimens) from start to finish, in sequential order. Include details of all the following, as applicable:

- *Research measures/tests/data collection tools that will be used.* ***Upload copies of all surveys, interview guides, assessments, questionnaires, and any other data collection tools to UTRMS-IRB in the "Other Attachments" section.***
- *Research interventions and activities, including all stimuli/tasks/instructions that participants will see, hear, or experience as part of their participation.* ***Upload copies of all intervention materials (including videos, audio files, handouts, photos, scripts, etc.) to UTRMS-IRB in the "Other Attachments" section.***
- *Descriptions of any equipment that participants will be asked to use, wear, or otherwise interact with for research. Upload any relevant instructions, manuals, pictures, etc. that may help to illustrate what participants will experience.*
- *Biospecimens that will be collected as part of the research procedures, including the type of specimen, method of collection, schedule/frequency of collection.*
- *Secondary data or specimens that will be obtained, how they are collected and used, from what source(s).*

- *Total duration of all research activities (i.e. expected time commitment of participants).*

Note: if this is a Multi-Site or Collaborative Study include the following:

- *This is a "Multi-Site Study that involves more than one site performing ALL aspects of the research procedures as outlined above." OR "This is a Collaborative Study that involves UT Austin researchers working with external researchers who are engaged in performing the following study activities (list activities)."*
- *For assistance with Multi-Site/Collaborative research, review UT Guidance: Submitting Studies Relying on UT IRB, download HRP-UT932 Request to Rely Assessment Form from the UTRMS-IRB Library and email irbreliance@austin.utexas.edu.*

This is a multi-site study; UT Austin will be the reliance single IRB (sIRB) and the participating sites (pSites) will include McGovern UT Health Houston and UTMB Galveston. We anticipate 25 pregnant participants from each site. We will be recording study activities in two REDCaps; the WombWatch Pilot Study Screening REDCap, to capture enrollment/screening activities and the WombWatch Pilot Study Enrolled, to capture Baseline Enrollment, Ongoing study activities and Study End/Postpartum activities.

75 pregnant participants in total (mixed population of low-risk and high-risk pregnancies) will be approached at 28-32 weeks' gestation to participate in the study during a regularly scheduled doctor's visit. Potential participants can also scan the QR code on the study flyer, to be posted at each site. Whether they are approached in clinic, or scan the QR code, potential participants will complete the WombWatch Pilot Study Screening REDCap tool, also called the WombWatch Study Interest & Eligibility Screening Form.

The following will be viewed by potential participants:

WombWatch Study Interest & Eligibility Screening Form

Study Title: WombWatch Prenatal Monitoring Study

Principal Investigators: Kenneth Moise Jr., MD; Kelly Gaither, PhD (UT Austin)

Co-Investigators: Jerrie Refuerzo, MD (UT Houston) and Corey Clifford, DO (UT Galveston)

Thank you for your interest in our WombWatch App Study. We are exploring whether a smartphone application can "hear" fetal movement. We are interested in finding out how we can use smartphones to help with prenatal care. Many people have smartphones, and healthcare providers have already figured out how to use features of them for other medical specialties. We are curious to know if pregnant people can use them to help confirm movements from their unborn baby. This study is testing that out by using the microphone of a smartphone and the Womb Watch application.

If you decide to participate, you will be asked to record your pregnant belly for 15 minutes per day, from the time of enrollment to the day of delivery. You must be between 28-32 weeks pregnant at the time of enrollment. You will be asked to complete up to 6 surveys, one at the time of the enrollment, one every 4 weeks, and two within 7 days of your delivery. We are offering up to $200 in gift card compensation.

You are being asked to complete this short form to determine whether you may be eligible for our research study evaluating a smartphone app used during pregnancy.

Completing this form does not mean you must participate. If you are eligible and interested, study staff will contact you with more information. Your responses will be kept confidential and used only for research screening purposes.

They will then be asked the following questions:

Please indicate if you are an interested potential participant or study staff member completing this interest form on behalf of a clinic patient: They will select Potential Participant or Study staff member.

Are you interested in learning more about this research study? : They will select Yes or No.

Following these two questions is the Eligibility Screening, to include the following questions:
Which of the following study centers do you live closest to? They will have the following options as answers: Dell Medical School – UT Austin, McGovern Medical School – UT Health Houston, University of Texas Medical Branch at Galveston, or None
How many weeks pregnant are you today? : They will have the following to choose from <24wks, 24-27wks, 28-32 wks, More than 32 weeks, Not Sure
Is this a single pregnancy (one baby)?: They can select Yes, No or Unsure
Do you currently own your own smartphone? (Any make or model): They can select Yes, No or Unsure
Have you ever been diagnosed by a healthcare professional with an anxiety disorder (such as generalized anxiety disorder, panic disorder, or similar)? : They can select Yes – I have or have had an anxiety disorder, No – I do not have nor have had an anxiety disorder, Prefer not to respond

If they meet the screening criteria, they will receive the following message: Based on your answers it appears that you may be eligible for participation in our longitudinal study! If you would like to be contacted by a study staff member for follow-up, please complete the following contact information form. Your responses and contact information will be kept confidential and only used by study staff.

They will then be asked to complete their contact information. They will be prompted to *Only complete this section if you would like to be contacted about the study.* They will be asked to give permission to contact them.

I give permission for study staff to contact me about this research study
Please note that we will not contact you unless you indicate we are permitted to do so!

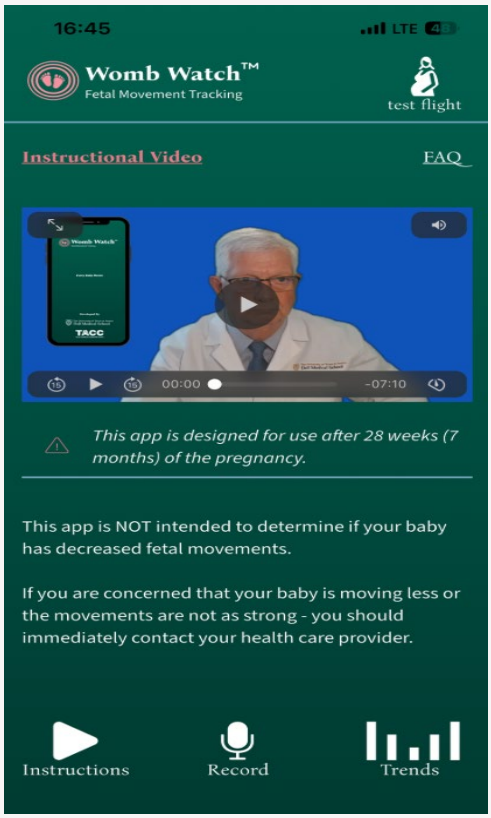
They can select Yes or No.

They will then be asked to provide their First & Last Name, Phone number, Email address, preferred method of contact (call, email, no preference) and if there's a preferred time for the study team to contact them. Lastly, they will complete Today's Date. The final message they will see is the following: Than you for your interest in our study. If we are still enrolling at your clinic site, a member of our study team will contact you with further information!

A study coordinator will be notified via email anytime an individual completes this REDCap Screening tool. If a potential participant did not scan the flyer QR code, but rather were approached in clinic, the study coordinator must complete the REDCap Screening tool with them if they are interested in participating. This is to capture how many potential participants are approached, if they enrolled or not, and if not, what criteria they did not meet. Study Coordinators will complete the REDCap Screening Tracker when they contact potential participants. Study coordinators will record each attempt made to contact potential participants, up to a maximum of three attempts. Study coordinators will record the outcome of contact, i.e. did they decline, schedule to be consented, ask for follow-up, no contact made-left message, or incorrect contact information.

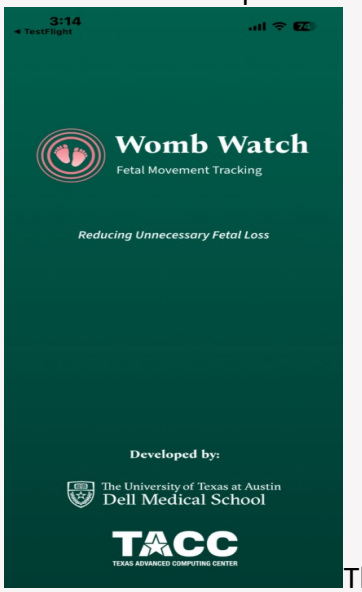
If a screened participant wishes to enroll, they will schedule a 15-to-30 minute, in-person appointment at their healthcare provider's site with a designated study coordinator. During this visit the study coordinator will review the consent before any study activities transpire. The consent is embedded within the WombWatch Pilot Study Enrolled REDCap. The study coordinator will select the Study Site to populate the site-specific consent form. Signed, written informed consent will be obtained in-person by a study coordinator on an Apple iPad within the HIPAA-compliant Dell Med REDCap Womb

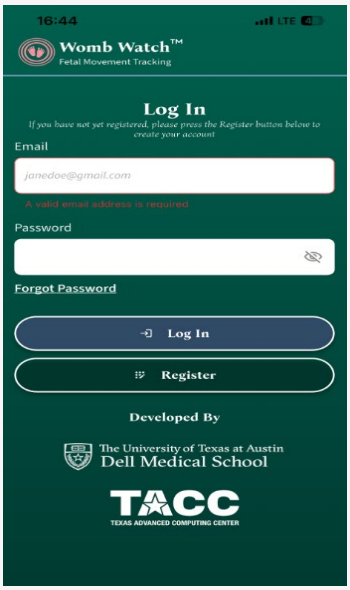
Watch database. It will be emphasized that any results from the Womb Watch app are experimental and are not diagnostic. Participants will then complete a Generalized Anxiety Disorder survey (GAD7) to ensure eligibility. If participants score a 10+ on their GAD7, they will be excluded from the study and will not be provided access to download the Womb Watch application. Study coordinators will not disclose GAD7 results to participants. The local PI or Co-I will be consulted for elevated GAD7 to ensure a participant receives appropriate follow-up, as needed. If they qualify to participate, they will then be asked to download the prototype Womb Watch application to their personal smartphone. iPhones and Androids of any generation may be used. Participants must own a personal smartphone with internet capabilities. While the app is downloading, they will be asked to view the Instructional Video on the iPad. The same video is in the "Instructions" tab of the WombWatch app, as seen below:



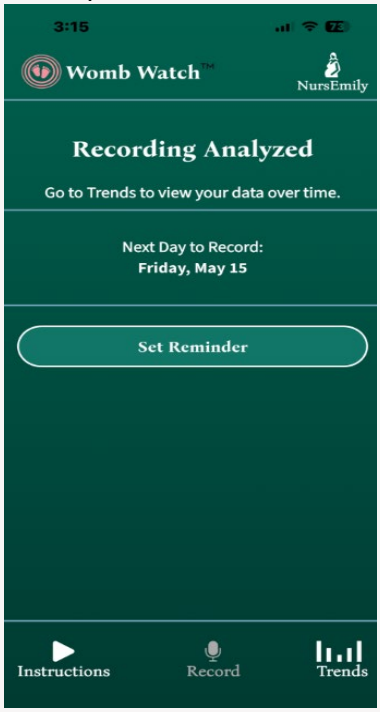
When a participant opens the application for the first time they will be provided with various options for setting up the app. These include written instructions and/or an animated instructional video. The SC will assist with the initial setting up of the app. Participants will register/sign up on the app and must choose their own username and password. They will be asked to provide their phone number for a two-factor authentication, which will be a 6-digit number sent via text. Participants will complete two-factor authentication each time they log out or are logged out of the Womb Watch app. Additionally, the app requires that the participant provides a current email address. This is critical to study participation because participants will receive email notifications for future surveys or if there's been a lapse in recordings. The following participant data will be stored encrypted on the UT TACC Firestore database: email address, phone number, Participant ID, audio recordings, and Likert Scale assessment of fetal movement strength. Participant data that will be stored in the HIPAA-compliant, encrypted Dell Med REDCap WombWatch Pilot Study Enrolled database will include demographics, usability statistics, GAD-7 surveys, and clinical outcomes of pregnancies. Participating sites will have REDCap User logins with restricted access to the WombWatch Pilot Study Screening REDCap and the

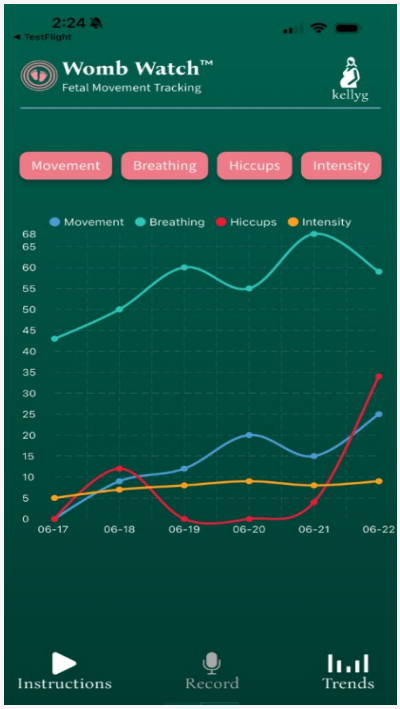
WombWatch Pilot Study Enrolled REDCap for data entry. No study data or activities will be recorded or stored outside of UT Dell Med REDCap and the UT TACC database.

The Home Screen: 

The login/registry screen: 

Within the application, participants will be able to view their trends, to include fetal movement, fetal breathing, fetal hiccups and the intensity scores they've completed using a Likert scale. A disclaimer will notify participants that the values/trends are not diagnostic, that the app is experimental only. This is also reiterated in the consent at the time of enrollment. The x-axis provides the Date of the recording, the y-axis the number of supposed fetal movements. After a recording is completed and transmitted to TACC for analysis, participants will be able to view their trends within 5-10minutes. Participants can choose to set a reminder for their next recording, it is optional.





All participants will utilize the Womb Watch smartphone application from enrollment baseline until delivery. Participants will be asked to use Womb Watch for 15 minutes daily, preferably in the evening at a time of their choosing. During recordings, participants will not be able to view social media or accept phone calls. They will view a countdown of the recording time until completion. An example is below:



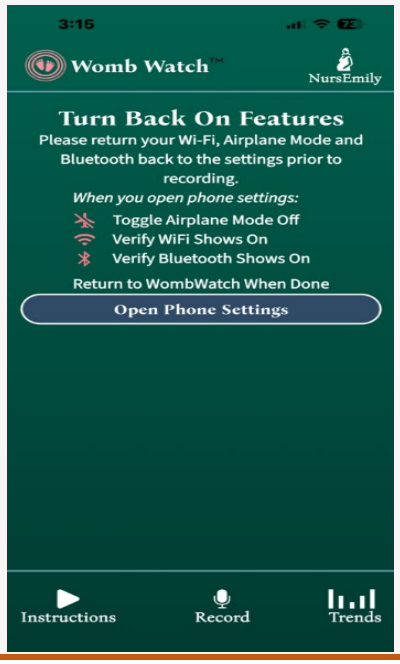
Participants will be informed during consent that the smartphone will record more than just the fetal movement sounds and that they should record in a quiet space with minimal conversations. In addition to the intended recording of sounds produced by fetal movement, the app will record all audible sounds. Participants will be informed that audio files which are transmitted to TACC for analysis will be deidentified and the sounds recorded will not be traceable back to them—only the frequency of sound associated with fetal movement sounds will be analyzed. In situations where an audio recording is complicated by noise disruptions in the environment, participants will have the option to delete the recording and re-record a new audio file. The app is designed such that no more than one audio file will be on their phone at a given time. If it's too loud or if a recording is not being

captured, participants will get a “Recording Failed” notification, seen below:



Just prior to recording, the app will prompt the participants to turn off their Wifi and Bluetooth features and enable the “Airplane Mode”. While radio frequencies emitted by smartphones have not been associated with effects on the fetus, the study team wants to be as careful as possible and recommend turning the smartphone into essentially a listening device during recording sessions. This is strictly optional and the participant does not have to turn off Wifi and Bluetooth and turn on Airplane mode to participate or make a recording. After the recording, the participants will be prompted to turn their Wifi and Bluetooth back on and disable “Airplane Mode”.





Participants will then be asked to complete a Likert scale assessment of the Intensity of the Movements they experienced during the recording session. This maternal assessment will be included in the "Trends" section of the app for review by participants.



Study coordinators will contact participants by phone every two weeks to check in to ensure the app is functioning correctly and to answer any participant questions. Participants can always find study team contact information on their consent but also under the FAQ section of the app itself, should they have a question/concern between check-ins'. All app usage and audio recordings will be maintained within the WombWatch Pilot Study Enrolled database. If a participant fails to use the app for 3 consecutive days, the participants and study coordinators will receive an automated email reminder from the REDCap database prompting to record another fetal movement assessment. This will be site specific notification, e.g. if a UT Dell Med participant has not recorded for 3 consecutive days, the participant and the site-specific coordinator will be notified. If a participant fails to use the app for another 3 consecutive days, the participants and study coordinator will receive a second automated email reminder to record using the app. If a participant fails to use the app for 7 consecutive days, the study coordinators will be notified via email from the database. Study coordinators will then contact the participants by phone to determine if they are still interested in participating and/or determine if they are still pregnant. If a participant is unable to be reached after 3 automated reminders are sent, they will be considered lost to follow up and removed from the study. In addition, study coordinators will be responsible for capturing any changes in pregnancy so that the study team can determine if the app analysis is beneficial to, or coincides with, the care of pregnant patients. This will include prenatal records, ultrasound reports, delivery records and neonatal delivery summaries.

Participants will be asked to complete up to four GAD-7 surveys—one at the time of enrollment, and again every 4 weeks while using the app. The number of surveys will vary by participant, depending on their gestation at enrollment. Participants will be sent a link to the surveys via text message or to their personal email. Survey responses will be recorded automatically in the WombWatch Pilot Study Enrolled REDCap database. Links to the surveys will not expire. The GAD-7 survey is included with this submission under Additional Documents. If the participant's GAD-7 scores are elevated (scoring 10+) they will be flagged for behavioral health follow-up by a study coordinator, referred to clinical care, or

removed from the study if clinically appropriate to the discretion of the PI. GAD7 scores will not be disclosed to the participants. Once a participant delivers their baby, they will be asked to complete a final GAD-7 survey and a Usability survey within 7 days. Participants will then be asked to remove the app from their personal device.

This is a Multi-Site Study that involves more than one site performing ALL aspects of the research procedures as outlined above.

8. Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

Audio signals will be registered by the participant using the microphone of the smartphone held vertically against the pregnant uterus. Different models and brands of smartphones, with or without smartphone cases, will be compared in the TACC deep learning/machine learning model. In addition, the gyroscope and accelerometer sensor data will be captured for assessment of maternal abdominal wall movement. This is to assess gross motor movements of the fetus, such as a kicsk. The audio, gyroscope and accelerometer files will be uploaded from the Womb Watch app via Google Firestore to an encrypted database at the Texas Advanced Computing Center (TACC-UT Austin). The model is investigator-developed by Co-I, Dr. Kelly Gaither and internally hosted by UT TACC.

A deep learning/machine learning model will be employed to determine the number of three categories of fetal movements based on these files: gross body movements, fetal breathing and fetal hiccups. The participants will be asked to assess the strength of fetal movements after each recording session using a Likert scale in the app. Amniotic fluid levels, based on routine clinical ultrasounds, will also be incorporated into the model to assess their effect on audio signals.

We will analyze composite scores from the GAD-7 scoring tool across timepoints in each patient using multilevel modeling.

Study Elements Requiring Additional Information or Approvals

9. Public Registration and Reporting Requirements

Federal regulations, policy, and some journal guidelines require public registration and results reporting for studies that meet the definition of a clinical trial.

Note that the various definitions of "clinical trial" subject to these requirements can be quite broad and include things like behavioral interventions conducted outside of traditional healthcare settings.

Answer the following questions and review the linked guidance to see if any of these requirements apply to this study.

9a. Does this study involve prospectively assigning participants, or groups of participants, to <u>one or more</u> research intervention(s)?

<u>Intervention</u> includes both physical procedures by which data/specimens are gathered and manipulation of the participant or the participant's environment for research purposes. Can include control groups.

☐ No → *Skip to item 10*

☒ Yes

9b. Is the intention of the study to evaluate the effect of a research intervention on *health-related* biomedical or behavioral outcomes?

☐ No → *Skip to item 10*

☒ Yes

9c. If yes to the above, go to UT Guidance on Clinical Trials Registration and Results Reporting and review requirements that may be applicable and select which of the following apply to this study:

☒ Intended to be submitted for publication in a journal subject to International Committee of Medical Journal Editors (ICMJE) requirements

☐ NIH-funded Clinical Trial *(be sure list funding on the Study Funding section of the UTRMS application)*

☐ FDA-defined Applicable Clinical Trial

☐ Intended to have routine clinical trial costs covered by the Center for Medicare and Medicaid Services (CMS)

☐ Registration is required per the terms of the award/funding agency

☐ Meets none of the above requirements but will register voluntarily

☐ None of the above

9d. Will the UT Austin study team register this study on ClinicalTrials.gov?

Click here for information on how to identify the "Responsible Party" for registration.

☒ Yes

☐ No – This is a multi-site study and the UT PI is not the Responsible Party for registration. The external Responsible Party is aware of their duty to register the study.

☐ No – This study involves an IND or IDE held by someone other than the UT PI, the IND/IDE holder is the Responsible Party and is aware of their duty to register the study.

☐ No – This study meets none of the requirements in item 9c above and the study team prefers not to register

9e. Attest that all relevant reporting requirements for the study will be followed as applicable (regardless of ClinicalTrials.gov registration).

Use the linked guidance in item 9c and review the section titled "Reporting Results" for guidance. This box must be checked to confirm you have reviewed the requirements, even if you determine no reporting requirements apply to you.

☒ Confirm

10. Does the research involve biospecimens of any kind (e.g. blood, tissue, saliva, etc.), biohazards, recombinant DNA, or gene transfer?

☒ No → *Skip to item 11*

☐ Yes

10a. Does the research involve human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos?

☐ No

☐ Yes → *Be aware that additional review criteria may apply, see UT IRB Policies & Procedures section 18 for guidance.*

10b. Will biospecimens be used and stored at UT?

☐ No, biospecimens collected will be stored at an external site that has responsibility for biosafety

☐ Yes → UT Institutional Biosafety Committee (IBC) approval *is needed. Provide the UT IBC number in the text box below:*

10c. Does the research involve prospective collection of blood from participants?

☐ No → *Skip to item 11*

☐ Yes

10d. Select all methods that will be used to collect blood samples:

Note that procedures for all forms of specimen collection should be described in the Study Procedures section above. The IRB requires the following specific details for blood collection to determine the appropriate review level.

☐ Research sample collected at the same time as non-research blood collection (i.e. extra blood collected)

☐ Individual needle stick(s)

☐ Indwelling catheter placed solely for this study

☐ Accessing indwelling catheter placed for non-research purposes

☐ Other, specify in text box below:

10e. Specify the timing and frequency of blood collection and the volume of blood obtained at each collection:

11. Does the research involve genetic testing/analysis?

This may include research involving identification and location of specific genes, study of gene products, inherited human traits, or identification and analysis of DNA mutations.

☒ No → *Skip to item 12*

☐ Yes

11a. Describe the genetic testing/analysis involved in this study:

If this is already described earlier in the form (such in the Study Procedures or Data Analysis items), please reference the appropriate sections where this can be found in the box below.

11b. Are participants able to opt-out of or withdraw from the genetic testing part of the research while continuing with other parts of the research?

Be sure this response aligns with language included in the consent form(s).

☐ Yes

☐ No

11c. Will or might genetic testing/analysis reveal clinically relevant findings for participants?

For example, medical conditions that could be treated or information about paternity/lineage.

☐ No → *Skip to item 12*

☐ Yes → *Describe potential findings below:*

11d. Describe the procedures for providing clinically relevant genetic results to participants:
Include whether or not genetic counseling will be offered to participants. Specify whether or not participants will be offered the option to decline learning the results, or if any results will not be provided (and if so, why). Be sure this response aligns with language provided in the consent form(s).

11e. Will genetic tests be run in a CLIA-certified laboratory?

☐ Yes

☐ No → *If no, explain below why this is not necessary:*

12. For this study, will the researchers obtain, use, or disclose Protected Health Information (PHI) regulated under the Health Insurance Portability and Accountability Act (HIPAA)?
This typically applies to research involving access to medical records. This does not include self-reported health information disclosed as part of research surveys/interviews. Guidance on HIPAA protected PHI is available here.

☐ No → *Skip to item 13*

☒ Yes

12a. Select all HIPAA-covered entities providing PHI:

☐ UT Health Austin
☐ UT Austin University Health Services
☐ CommUnity Care
☒ Ascension Seton/other Ascension locations*
☒ Dell Children's Medical Center*
☐ Central Health
☒ Other, specify: McGovern Medical School at UTHealth Houston, UTMB – The University of Texas Medical Branch

***For studies obtaining data from Ascension facilities,** please submit a request to the Seton Site Approval Tool (SAT) and upload the confirmation email that states the request has been submitted in UTRMS under "Other Documents." Please note, we do NOT need the final approval letter (you will not receive SAT approval until after IRB approval is granted). If you encounter issues or have questions about SAT, please reach out to siteapproval@seton.org.*

12b. List the data points or attach a list of the data to be collected about each subject from their medical records or other HIPAA protected data source(s). *Select one of the following:*

☐ This list is uploaded to UTRMS on the Local Site Documents page under "Other Attachments"

☒ All data points listed in the text box below:

- Name
- Date of birth
- Phone number
- Past pregnancy history
- Baseline and periodic GAD-7 anxiety scoring tool
- Ultrasound reports (date of exam, estimated fetal weight, amniotic fluid volume (AFI).
- OB risks and/or problems
- Expected due date
- Height

- Pre-pregnancy weight
- Weight at enrollment, every 4 weeks, and at delivery
- Race
- Ethnicity
- General pregnancy history
- Model and version of smartphone being used with application Type of smartphone case being used with application
- Delivery records to include gestational age at delivery, reason for delivery, method of delivery, Apgar scores, blood cord gases, birthweight, fetal sex, neonatal course of care

12c. Select all pathways for obtaining HIPAA authorization for accessing PHI for this research:
NOTE: If obtaining authorization from Ascension patients, use of Ascension's stand-alone HIPAA authorization form is required and this form should be uploaded on the Local Site Documents page in UTRMS under "Other Attachments." Otherwise, non-Ascension HIPAA authorization may be combined with Informed Consent using the HIPAA template language embedded within the 920 Standard Consent Template. All UT Austin IRB templates are available in the Templates tab of the UTRMS-IRB Library.

☒ Obtaining HIPAA authorization from participants to access PHI → *Skip to item 13 if only this box is checked*
☐ Requesting *full* waiver of participant authorization
☒ Requesting *partial* waiver of authorization to access PHI for screening or recruitment only
All of the following must be checked to qualify for a partial waiver for screening or recruitment:
- ☒ Attest that PHI will be accessed ONLY to identify eligible subjects for recruitment in this research. Continued access to PHI will be limited to those who later volunteer for the study and provide written authorization.
- ☒ Attest that PHI will be accessed only by individuals who have authorization to access the records outside of the research context.
- ☒ Attest that researchers will not move or transmit identifiable PHI from the covered entity (i.e. the institution holding the records, such as the clinic).

12d. Complete the following if requesting a *full or partial* waiver of HIPAA authorization:

I. Specify the date range of records that will be accessed:

Start date (month/year):	June 2026
End date (month/year):	January 2028

II. Provide a justification for why the research could not practically be conducted without access to PHI and the waiver of patient authorization requested:

☒ Identification/recruitment: *– access to records is needed to identify eligible subjects (e.g., chart reviews, partial waiver for recruitment, etc.)*

☐ Large number of subjects projected *– potential subject population includes a large number of records to review and it is not feasible to attempt contact with all subjects*

☐ Outdated records *– This is a retrospective study involving subjects who may have moved or expired and researchers cannot feasibly attempt to contact required sample*

☐ Total population required - *The nature of the research is such that findings will not be valid, or will be significantly skewed, if the total eligible population is not included.*

Select all that apply above OR provide different justification below.

☐ None of the above; specify other justification:

Note that inconvenience or limited time/resources alone are not sufficient justifications for waiving a patient's right to authorize disclosure of their PHI.

III. Attest that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research where the use or disclosure of the PHI meets IRB and HIPAA requirements.
This box must be checked.
☒ Confirm

IV. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Review the linked guidance and attest below that you are obtaining only the minimum information necessary to complete the waived activities:
This box must be checked.
☒ Confirm

V. Provide any additional information you'd like the IRB to consider for why/how all the listed data points in item 12b are necessary to answer the research question and comply with the minimum necessary requirement described above *(if none, this can be left blank):*

13. Does this study involve Deception and/or Incomplete Disclosure?

See IRB Policies and Procedures Section 15 for a description of deception.

Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.

Incomplete disclosure means that the investigator withholds some information about the real purpose of the study or the nature of the research procedures.

☒ No → *skip to item 14*
☐ Yes → *Note that an alteration of informed consent may need to be requested in the Consent Pathways section. Please address items below:*

13a. Describe the nature of deception/incomplete disclosure and why it is necessary to conduct the research.

13b. Will participants be debriefed (i.e. provided additional pertinent information about the nature of the deception/incomplete disclosure) after research activities are completed?
☐ Yes
☐ No → *provide a strong justification below for why this will not occur, then skip to item 14:*

13c. Describe debriefing procedures.

NOTE: Upload the debriefing form to UTRMS-IRB in the "Local Site Documents" section.

13d. Will research participants have the opportunity to withdraw their data during/after debriefing?

☐ Yes → *Be sure to include language about this option in the uploaded debriefing script.*

☐ No → *Provide a strong justification below for why this will not occur:*

14. Research Activities Requiring Supplemental Forms or Additional Oversight

Select each of the items below that are relevant to your research. If none apply, this section can be left blank.	*For each item selected, complete and upload the associated Supplemental Form in UTRMS-IRB under "Other Attachments" or review the linked guidance and follow instructions as applicable.*
☐ Investigational Drugs, Biologics, Supplements, or other regulated non-device products	UT Supplement 906 – Investigational Drugs, Biologics, and Non-Devices
☒ Investigational Device	UT Supplement 905 - Investigational Device
☐ Research conducted outside the U.S. and/or involving international participants or subjects ☐ Research conducted in and/or involving collaborators in countries of concern.	UT Supplement 908 - International Research *The linked supplement is required for research conducted outside the US, direct remote interactions with international participants (i.e. Zoom interviews), and research that will collect identifiable data from international participants (including online surveys).* *Be aware that any UT investigator contemplating or already working with entities or individuals in countries of concern or conducting research in those countries should reach out to the Research Security team and complete any required reviews (e.g., International Collaboration Review Committee (ICRC) review) at their direction prior to starting the research.*
☐ Department of Defense (DoD) *This includes all research involving DoD funding, facilities, data, or personnel (i.e. active military personnel are targeted/discernible in the data collected). See Policies & Procedures section 25.1 for guidance on DoD applicability.*	UT Supplement 911 - Department of Defense
☐ Energy introduced to the subject (electrical, magnetic, light) ☐ Radiation exposure without direct clinical benefit	*For research involving these activities, be aware that the IRB may solicit ancillary review from the UT Austin Environmental Health & Safety (EHS) office. Any additional requirements may be communicated during review. Guidance on EHS policies and reviews is available here: IRB-ML101-Guidance for Institutional Reviews and Approvals of Human Research at UT Austin (PDF).*

☒ Use of Artificial Intelligence (AI) in research	*As part of UT ISO's mission and with the growing use of AI in research, all research that involves use of AI should be in alignment with ISO's Acceptable Use of AI Policy.* *If your AI platform use is not listed or in alignment with the policy above, contact UT ISO at security@utexas.edu prior to conducting any research with that AI tool. It is strongly recommended to confirm acceptability prior to submitting to the IRB.*

Subject Population

15. Sample Size

Enter the maximum total anticipated sample size, including a breakdown of target sample size per participant group (if more than one). Note that the IRB is looking for the number of individual human subjects you plan to enroll.

75 total participants to be included in the study. We intend to recruit 25 participants from each of three sites.

16. Sample size rationale

Describe your sample size rational below.

This is the number believed to provide adequate feasibility data for the real-world use of this app.

17. Research Participant Information

Describe the general characteristics of the subject populations or groups including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g. teachers and students), clearly outline characteristics for each group.***

Pregnant patients with a gestational age of 28 – 32 weeks at the time of enrollment with singleton pregnancies.

18. Age range (minimum and maximum)

Include the age range for target population. If there is no maximum age, this can be noted, but a minimum age required for inclusion must be explicitly stated. If you have multiple research populations, clearly state the age range for each group.

Age 18-45 years old.

20. Inclusion/Exclusion Criteria

Describe the specific criteria that will be used to decide who will be included in and excluded from the research from the population of interested or potential subjects. Define technical terms in lay language, as applicable.

Inclusion criteria:

- Ability to understand and voluntarily provide written signed informed consent to participate in the study.

- English speaking (the alpha version of the Womb Watch app is only available in English)
- Singleton intrauterine pregnancy
- Estimated gestational age at enrollment 28 weeks to 32 weeks
- Low-risk pregnancy with normal fetal growth and anatomy and no maternal co-morbidities of note.
- High-risk pregnancy including fetal anomalies and maternal co-morbidities including but not limited to cardiovascular, pulmonary, hepatic, renal, hematologic, gastrointestinal, endocrine/metabolic, immunologic, dermatologic, neurologic, or oncologic.
- No prior diagnosis of an anxiety mood disorder or a psychiatric illness
- Access to internet
- A functioning email address

Owns personal smartphone; iPhone or Android of any generation

Exclusion criteria:

- Currently pregnant with multiples (twins or more)
- Baseline GAD-7 score of 10+

21. Justification for Target Population(s)

If the inclusion/exclusion criteria target or exclude a particular segment of the population(s) relevant to the research topic, provide a rationale for why this target population is appropriate to address the research questions. Specific groups should not be targeted for research based solely on convenience/availability.
*For example, if **only** UT students are targeted for research affecting a broader population, explain why this is equitable and appropriate for this study.*

- Participants must be 18 years or older. We do not believe a minor would be motivated to participate in such an involved study requiring daily participation.
- Participants must be English-speaking, as the alpha version of the Womb Watch app is only available in English.
- The AI model was trained on singleton pregnancies only. It does not have functionality for multiple fetuses in a pregnancy.
- The definition of late stillbirth begins at 28w gestation. This is a milestone in pregnancy when patients are often counseled to be aware of their fetal movements.
- A variety of pregnancy conditions from uncomplicated to complicated will provide more data related to variables which might affect app usability.
- If a prospective participant has a history of anxiety, mood disorder, psychiatric illness, or they score 10+ on the GAD-7 survey, they will be excluded due to inability to effectively compare their behavioral health throughout the study with participants who do not have that history.
- Participants must own a personal smartphone of any make or model older and have internet access because of research funding constraints. It is not within our budget to provide all participants with a smartphone and ensure they have internet connection.
- Participants must have a functioning email address to receive correspondence from the study team as well as compensation.

22. Will the study involve recruitment of the researchers' students or personal contacts/friends/family?

☒ No → *Skip to item 23*

☐ Yes → *Explain below how the study procedures will be designed to mitigate potential for coercion or undue influence to participate or continue participation:*

23. Will you recruit or obtain data from individuals you know to be prisoners?

*"Prisoner" is defined in federal regulations under **45 CFR 46.303(c)** as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."*

☒ No → *skip to item 24*

☐ Yes

23a. Provide the rationale for including this population in your research *(i.e. why is a prisoner population necessary to answer the research questions)***:**

23b. Describe how study procedures will be designed to address each of the following:

(a) Recruitment and subject selection procedures will be fair to all eligible prisoners;

(b) Prison authorities or other prisoners will not be able to arbitrarily prevent or require participation of particular prisoners;

(c) When applicable, control subjects will be randomly selected from the group of available prisoners meeting inclusion criteria (or provide a justification if selection will not be random);

(d) When applicable, provisions will be in place to provide follow-up examinations or care of participants, taking into account the varying lengths of individual prisoners' sentences, and all participants will receive information about how this will occur.

23c. Describe how you will mitigate potential for undue coercion for prisoners to take part in the study:

Consider whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison might be so great as to make it difficult for prisoners to adequately consider the research risks.

23d. Check the appropriate box(es) to attest to the following:

☐ Researchers for this study will not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions.

☐ When applicable, each prisoner will be clearly informed in advance that participation in the research will have no effect on his or her parole. *(Consider adding language about this in the relevant consent form(s))*

24. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems may be likely to have subjects who will be prisoners at some point during the study.

☒ No → *Skip to item 25*

☐ Yes

24a. If a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

☐ No

☐ Yes → *Describe the procedures and/or data collection you plan to continue with prisoner subjects:*

25. Other Protected Populations

*In this section, check the box for **all other protected groups that will be intentionally targeted/discernible in your research** (you do **not** need to check all groups that might be* incidentally *included but will not be knowingly enrolled or discernible as a population of study from the data collected).*

Select all that apply to this research. If none apply, this section can be left blank.	*Review the special considerations for selected group(s).*	*Provide the rationale for targeting this protected group in your research. If this has already been addressed in item 21 above or elsewhere, reference earlier responses here, as applicable.* *Also, include any additional information you'd like the IRB to consider when reviewing additional requirements outlined in the linked policy(ies).*
☐ **Minors (children)** ☐ **Children who are wards of the state** *Note: children are considered subjects of the research if:* *1) the study involves collecting data about a child through an intervention or interaction with the child (regardless of identifiability of the data),* ***OR*** *2) private, identifiable information about a child is collected from any source (e.g. interview with parent, medical records, educational records, etc.).*	*Review for additional IRB considerations:* UT Austin IRB Policies & Procedures section 12.4: Research Involving Children UT Austin IRB Policies & Procedures section 12.4.9: Wards *NOTE: In the Consent/Assent Pathways section of this form, you will need to complete items **29 and 30** to address special consent/assent considerations and waiver options for minors.*	
☐ **Impaired/Incapacitated Adults** *Check this box if researchers will knowingly and prospectively enroll adults with conditions that impact their ability to make decisions for themselves and/or adults who are unconscious or incapacitated due to illness or condition.*	*Review for additional IRB considerations:* UT Austin IRB Policies & Procedures section 12.5.1: Research Involving Decisionally-Impaired Adults *NOTE: In the Consent/Assent Pathways section of this form, you will need to complete items **29 and 31** to address special consent/assent considerations and waiver options for this group.*	
☒ **Pregnant women and fetuses** ☐ **Neonates of unknown viability** ☐ **Non-viable neonates**	*Review for additional IRB considerations:* UT Austin IRB Policies & Procedures section 12.2: Pregnant Women, Fetuses, and Neonates	We need to determine if pregnant participants enrolled can successfully utilize the smartphone Womb Watch application for the detection and classification of fetal movements.

Recruitment & Screening

26. Recruitment Procedures and Materials

*Select each type of recruitment method that will be used AND **upload copies of all materials to UTRMS-IRB in the "Recruitment Materials" section.***	*Describe the use of the selected method to recruit participants, addressing the specific points listed for it, when applicable.*	*Provide the schedule and frequency of recruitment attempts using this method, when applicable.*
☐ **E-mail/Letter** *Explain how emails/mailing addresses for potential subjects will be identified and obtained by the study team. Describe the initial invitation and any follow-up reminders, and address if there will be a way for recipients to opt-out of future emails. Templates should include subject line(s).*		
☒ **Flyer(s)** *Include the types of location(s) where these will be posted.*	Flyers with a QR code will be placed in prenatal clinics at the enrolling institutions	Once at the time of site initiation and upon request
☐ **Social Media/Web Posts** *Address which sites and accounts will be used to post ads. Templates should include all text/images that will be included in posts. Guidance for creating templates for social media recruitment can be found on our Education & Guidance webpage.*		
☐ **Text/Direct Messaging** *Describe sites/accounts that will be used. Explain how participants' contact information is obtained, when applicable. Templates should include the initial invitation and any follow-up reminders.*		
☐ **Study-specific Website** *This refers to websites created specifically for this research study. Templates should include screenshots/mock-ups of all aspects of the website that will be created; include all text/images.*		
☒ **In-Person or Phone Scripts/Presentations**	Pregnant patients will be approached in person at their	Recruitment will take place in a private/confidential room with a

Explain how phone numbers for potential subjects will be obtained by the study team, when applicable. If researchers will be cold-calling subjects, provide a rationale for why this method is needed to accomplish the research.	routine OB visit in the clinic office and provided with a study flyer. SC will only approach participants who meet inclusion criteria.	SC. The sites include the Comprehensive Fetal Care Center located at 4910 Mueller Blvd, Ste. 103, Austin, Texas 78723, UTHealth Houston located at 6410 Fannin St, Ste 210, Houston, Texas 77030 and UTMB Health Maternal Fetal Medicine, Clear Lake Campus at 250 Blossom St, 3rd floor, Webster, Texas 77598.
☐ **Research Recruitment pool** *Specify which pool will be used (e.g. SONA, Prolific, Amazon MTurk, etc.) and describe how offered studies are advertised to users. Provide templates of all researcher-provided advertising language that will be posted and confirm it meets the pool's standards for formatting, content, word limits, etc.*		
☐ **Newspaper ads/TV spots/Radio ads** *When applicable, include scripts and descriptions for planned ads; final versions can be provided in a modification after IRB approval.*		
☒ **Medical Record Review** *If your study includes identifying potential participants using PHI (e.g., a partial HIPAA waiver for recruitment is needed), note this here and be sure you have completed item 12 in the Study Elements section of this form to request a waiver.*	Members of the study team will review potential participants' medical records for eligibility criteria listed in item 20 of this form prior to offering them participation	For Screening purposes.
☐ **Other recruitment material/method**		

27. Screening Procedures

Describe the procedures to screen individuals to determine whether inclusion/exclusion criteria are met. Be sure to include the following specific details:

- *Will screening procedures occur before or after consent?*
- *For any screening data collected prior to consent, how will this data be used? For example, will it be used only to confirm eligibility, screen failure analyses, or will it be used to answer the research questions as well?*

Please upload all screening questionnaires/tools in the "Other Attachments" section in UTRMS.

Some screening procedures will occur prior to and after consent. Prior to consent, SCs will determine if a patient is English-speaking, pregnant with a single fetus, and their gestation is 28-32 weeks through medical record review with partial HIPAA waiver. Study coordinators will approach patients who meet inclusion criteria during their routine OB visits. If patients express interest, the study coordinator will schedule a 15-30-minute appointment at the OB clinic to discuss the consent form. Once the participant signs the consent form, the study coordinator will confirm their OB history and have the participant take the GAD-7 survey. If the participant's GAD-7 score is 9 or less, they will be provided a QR code to download the Womb Watch app. If their GAD-7 is 10 or higher, they will be excluded from the study and referred to their OB for behavioral health follow up.

Consent /Assent Pathways

28. Consent Pathways

Obtaining informed consent is the default expectation for enrolling subjects in non-exempt research. For all human subjects included in the research (either via direct participation or having their private, identifiable data included in the study), researchers must have a pathway either to obtain informed consent or request and meet criteria for waiving informed consent.

***Select all consent pathways that will be used to enroll subjects into the study**.*
Examples:
1) If you will obtain consent from one group of adult participants but are requesting a waiver for another group (such as a retrospective chart review group), both "Obtaining Consent from Adult Participants" and "Requesting Waiver" should be checked.
2) If adults will provide consent for their own participation and provide consent for their child's participation, both "Obtaining Consent from Adult Participants" and "Obtaining Parent/Guardian Consent for Minor Participants" should be checked, etc.

☒ Obtaining Informed Consent *(verbal or written)* from:
- ☒ Adult Participants for their own participation
- ☐ Parent(s)/Guardian(s) for Minor (child) Participants
- ☐ Legally Authorized Representative (LAR) for impaired/incapacitated adult participants

☐ Requesting Waiver or Alteration of Required Elements of Informed Consent
☐ Obtaining Short Form Consent with a witness *(rare, limited applicability, see Policies & Procedures section 6.4.2)*
[☐ FDA Exception from Informed Consent for Planned Emergency Research (EFIC) *(extremely rare, see P&P section 32 and contact regsupport@austin.utexas.edu for guidance on requirements before submitting to the IRB)*] → *Skip entire section and instead upload documentation describing the plan for public disclosure, community consultations, and other materials related to consent/enrollment to the Local Site Documents section in UTRMS-IRB.*

28b. Consent Signature Type

Select the method(s) for obtaining participant signatures for informed consent and describe these in detail in item 28c. Select all that apply to your research.

☒ Written Signature *(on paper or with finger/mouse/stylus on touchpad or computer)*
☐ Electronically-generated Signature using a standard validation service *(such as DocuSign or REDCap)*
☐ Electronically-generated Signature using a validation service confirmed to be Part 11 compliant → *see note:*
Part 11 compliance is required for studies falling within FDA regulations (i.e. investigational drugs/devices). Please be aware that not all UT system accounts for REDCap and DocuSign are compliant with the requirements of Part 11. Researchers conducting FDA-regulated studies at UT that wish to collect electronically-generated consent signatures must either 1) confirm account compliance with their department administration, OR 2) utilize an FDA-compliant account managed by an external sponsor or a collaborating institution (as applicable). Otherwise, written signatures must be obtained. For additional guidance on Part 11 compliance, contact regsupport@austin.utexas.edu.
☐ Obtaining consent without valid signature – waiver of signature requirement requested → *Complete both 28c and 28d*
☐ N/A - Not Obtaining Consent → *if not obtaining consent for any group skip to 28e*

28c. Obtaining Consent Description

In the box below, describe how each "obtaining consent" pathway and consent signature type checked in the items above will be used and with which participant group(s).

Be sure to include who will obtain consent, where consent will be obtained, when the consent process will occur so that participants have sufficient time for adequate consideration, how consent will be documented, and how signatures will be collected, when applicable (including what electronic signature platforms and processes will be used, whether forms will be emailed/mailed, etc.).

NOTE: Upload copies of all consent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.

During recruitment, study staff will provide potential participants with a verbal description of the study during their routine OB visit and provide them with a consent form for review. Study staff will ensure sufficient information has been communicated for potential participants to contemplate, ask questions, and make an informed decision about whether they would like to enroll. If the potential participant indicates interest in enrollment, a 15–30-minute screening/enrollment visit will be scheduled. Prior to setting up the app, participants will review the consent form with a study coordinator and sign it within UT REDCap. A participant ID will be assigned after informed consent is signed. The participant will then be asked to complete the GAD-7 baseline anxiety tool to be sure they qualify (a score of ≥ 10 would exclude the patient). The study coordinator will then assist the participant with downloading and opening the Womb Watch application onto their smartphone.

28d. Waiver of Documentation (signature) of Informed Consent → *if not requesting, skip to* **28e**

Only complete this section if you are requesting to waive the requirement to collect a written or validated electronic signature of informed consent from participants (an informed consent form/script is still required). To approve a waiver of documentation of consent, all criteria for one of the following options must be adequately justified by the researcher.

*Please choose **one** waiver option and address the listed criteria as prompted. **Waiver Option 1 is most common.***

i. Waiver Option 1 – Minimal Risk Research

Each criterion listed below must be met to qualify for Waiver 1.

Criterion 1: The study is minimal risk.

Provide protocol specific information as to how this criterion is met. Consider how the risk(s) of the research activity(ies) for which consent is being waived compare to the risks the average person might reasonably anticipate experiencing in everyday life:

Criterion 2: Written consent would not be required outside the research context.

Provide protocol specific information as to how this criterion is met. For example, if laws or other regulations requiring signed consent would normally be applicable to the type of research activity for which signed consent is being waived outside of a research context, this criterion is not met (e.g. consent for clinical care, consent for release of educational records, signing a housing application or similar contract, etc.).

Criterion 3: There will be an appropriate alternative mechanism for documenting that informed consent was obtained.
Briefly explain how the researcher will document that consent was obtained from participants:

ii. Waiver Option 2 – High Risk for Confidentiality Breach *(rare)*
Each criterion listed below must be met to qualify for Waiver 2.
NOTE: This is the only applicable waiver of documentation option for greater than minimal risk research. If your study is greater than minimal risk and does not meet Option 2 criteria, you will need to obtain signed consent.

Criterion 1: The only record linking the subject and the research would be the consent document.
Provide protocol specific information as to how this criterion is met.

Criterion 2: The principal risk would be potential harm resulting from a breach of confidentiality.
Provide protocol specific information as to how this criterion is met.

Criterion 3: Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
Provide protocol specific information as to how this criterion is met. Note that under this waiver, participants must be given the option to sign or not, so the consent form(s) will still need signature lines.

Criterion 4: There will be an appropriate alternative mechanism for documenting that informed consent was obtained.
Briefly explain how the researcher will document that consent was obtained from participants who do not sign.

iii. Waiver Option 3 – Cultural Norms *(rare)*
Each criterion listed below must be met to qualify for Waiver 3.

Criterion 1: The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm.
Describe the cultural group or community and explain how this criterion applies:

Criterion 2: The research presents no more than minimal risk of harm to subjects.
Provide protocol specific information as to how this criterion is met. Consider how the risk(s) of the research activity(ies) for which consent is being waived compare to the risks the average person might reasonably anticipate experiencing in everyday life:

Criterion 3: There is an appropriate alternative mechanism for documenting that informed consent was obtained.
Provide protocol specific information as to how this criterion is met and describe the mechanism for documenting that informed consent was obtained:

28e. Waiver or Alteration of Informed Consent Requested
Select the type(s) of consent waivers being requested or select "None requested".
Note this section is for requesting a full consent waiver or waiving part(s) of the required information typically provided in consent forms. Signature-only waivers are addressed in item 28d above.

Select all that apply.
☐ Waiver of Informed Consent for Adult Participants
☐ Waiver of Parental/LAR Consent for Child or Impaired/Incapacitated Adult
☐ Alteration of Required Elements of Informed Consent and/or Parental or LAR consent *(e.g. Deception research where the nature of the research cannot be fully disclosed)*
☑None requested → *Skip to item 29*

28f. Qualification for Waiver or Alteration
*To approve a waiver or alteration of informed consent **all of the following criteria below must be met.***

Criterion 1: The research involves no more than minimal risk to the subjects.
Provide protocol specific information as to how this criterion is met. Consider how the risk(s) of the research activity(ies) for which consent is being waived compare to the risks the average person might reasonably anticipate experiencing in everyday life:

Criterion 2: The waiver or alteration will not adversely affect the rights and welfare of the subjects.
Provide protocol specific information as to how this criterion is met. Consider whether this waiver may violate the rights of subjects or adversely affect their welfare in any way. For example, if the research proposes to use data that was originally collected under an explicit agreement that it would not be used for research purposes, this waiver might violate participants' rights.

Criterion 3: The research could not practicably be carried out without the waiver or alteration (i.e. the research would not be achievable or viable if obtaining consent is required).

Provide protocol specific information as to how this criterion is met. Acceptable justifications should be based on the study's scientific design rather than issues of time or inconvenience. For example, is there evidence to suggest significant portions of the sample would be unreachable and present significant sampling bias? Is the nature of the research such that a total population sample is necessary to answer the research questions?

Criterion 4: The research either does not involve using identifiable private information or identifiable biospecimens, **or** if identifiable data/specimens *are* used, the research could not feasibly be carried out without using such information or biospecimens in an identifiable format.

i.e. Why would it be impossible to conduct the study using only anonymous information/specimens? Provide protocol specific information as to how this criterion is met:

29. Assent Pathways for Research Involving Minors (children)

This section is required for all studies involving minors as subjects (see the Other Protected Populations section for guidance). If this study does not involve minors, skip to item 30.

Select all that apply:

☐ Obtaining Assent from Minor (child) Participants

☒ Not Obtaining Assent → *If only this box is checked, skip to item 29d*

29a. Minor Assent Signature Type

Select the method(s) for obtaining participant signatures for assent. Select all that apply to your research. Note that validation services such as DocuSign cannot be used with minors.

☐ Written Signature *(on paper or with finger/mouse/stylus on touchpad or computer)*

☐ Obtaining assent without signature for children age 12 and younger

☐ Obtaining assent without signature for children age 13-17 → *Complete both 29b and 29c*

☐ N/A - Not Obtaining Assent → *If only this box is checked, skip to item 29d*

29b. Assent Process Description

Provide a detailed description of assent procedures in the box below. Include: who will obtain assent, where assent will be obtained, how assent is obtained, how assent is documented (including details f how signature is obtained, if applicable), and when the assent process will occur.

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.

29c. Request to Waive Assent Signature Requirement for Minors (children) age 13-17 → *if not requesting, skip to item 29d.*

Only complete this section if you are requesting to waive the policy requirement to collect a written signature of assent from participants age 13-17. The IRB will assess the rationale provided by the researcher for appropriateness based on the specific study procedures and population.

i. Provide a protocol specific justification for why written assent signature will not be obtained:

ii. Describe the mechanism for documenting that assent was obtained.

Briefly explain how the researcher will document that assent was obtained from participants

29d. Waiver of Assent for Minors Requested

Note: Assent is generally not required for children age 0-6, so a waiver does not need to be requested for this age group.

☐ Waiver of Assent for Children age 7+
☒ None requested → *skip to item 29f*

29e. Qualification for Waiver of Assent from Minors (children) age 7+ *(select all that apply)*

☐ **Some or all children age 7+ included in this research will not be capable of providing assent based on their developmental status or impact of illness/condition**. → *If checked, explain below:*

☐ **Requesting a waiver of assent from some or all children age 7+ who are otherwise capable of providing assent** → *If checked, address all of the following. All of the following criteria must be met to request a waiver:*

Criterion 1: The research involves no more than minimal risk to the subjects.

Provide protocol specific information as to how this criterion is met. Consider how the risk(s) of the research activity for which consent is being waived compare to the risks the average child might reasonably anticipate experiencing in everyday life:

Criterion 2: The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Provide protocol specific information as to how this criterion is met. Consider whether this waiver may violate the rights of subjects or adversely affect their welfare in any way.

Criterion 3: The research could not practicably be carried out without the waiver or alteration (i.e. the research would not be achievable or viable if obtaining assent is required).

Provide protocol specific information as to how this criterion is met. Acceptable justifications should be based on the study's scientific design rather than issues of time or inconvenience.

Criterion 4: The research either does not involve using identifiable private information or identifiable biospecimens, **or** if identifiable data/specimens *are* used, the research could not feasibly be carried out without using such information or biospecimens in an identifiable format.

i.e. Why would it be impossible to conduct the study using only anonymous information/specimens from minors?
Provide protocol specific information as to how this criterion is met:

29f. Age of Majority Re-Consent Process

The age of majority is the age at which a person is legally considered an adult and can provide informed consent for their own participation in research. In most states, including Texas, the age of majority is 18, but this can vary depending on where the research is conducted.

If the research involves minors as subjects, either Option 1 or Option 2 below must be checked:

☐ Option 1: All study activities with minors will be complete AND all data collected from minors will be anonymized before any participants will reach age of majority.

☐ Option 2: The study enrolls minors who may reach age of majority while study activities and/or research use of their identifiable data is ongoing.

If true, specify the method of obtaining adult informed consent from these participants upon reaching age of majority. ***At least one of the following must be checked:***

☐ Participants will be re-consented using an adult consent form/script

Describe the re-consent procedures below. Be sure to upload an adult consent document that will be used for this group. If signature will not be collected (e.g. if re-consent is conducted via phone or other remote method), please complete item 28d to request a waiver of documentation (signature).

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section.

☐ A waiver of adult re-consent is requested in the Waiver or Alteration of Informed Consent section of this form.

30. Assent Pathways for Research Involving Impaired/Incapacitated Adults

This section is required for all studies where impaired/incapacitated adults are knowingly and prospectively enrolled (see the Other Protected Populations section for guidance). If this study does not involve this population, skip to item 31.

30a. Capacity for Consent/Decision-Making Capacity

Describe the process you will use (if any) to determine whether a cognitively impaired individual is capable of consent decision making with respect to this research protocol and setting.
Consent pathways for adults who are capable of providing full informed consent (instead of assent) should be covered in item 28 above.

30b. Impaired/Incapacitated Adult Assent Pathway *Select all that apply*

☐ Obtaining Assent from Adult Participant
☐ Not Obtaining Assent → *if only this box is checked, skip to item 31*

30c. Impaired/Incapacitated Adult Assent Signature Type *Select all that apply*

☐ Written Signature obtained when possible *(on paper or with finger/mouse/stylus on touchpad or computer)*
☐ Electronically-generated Signature obtained when possible, using validation service *(such as DocuSign)*
☐ Obtaining assent without signature

30d. Assent Process Description

Describe whether assent will be required for all or some of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not).
Provide a detailed description of assent procedures in the box below. Include: who will obtain assent, where will assent be obtained, how is assent obtained and documented (including details of how signature is collected, if applicable), and when the assent process will occur in such a manner that participants will have sufficient time for adequate consideration.

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp forms for approval.

30e. Re-Consent Process for Adults Who Regain Capacity to Consent

If the population includes adults who are incapacitated at the time of initial consent but may regain their capacity to consent while the study is still ongoing, describe the process for re-consenting these individuals for continued study participation and/or use of their identifiable private information/specimens for research. If this does not apply to your study, skip to item 31.

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section.

Additional Consent Considerations and Disclosures

31. Will the study population likely include participants whose limited English-speaking status requires translation of the consent/assent documents and other relevant study materials?

☒ No → *skip to item 32*
☐ Yes

31a. Translation Process

Complete the below information describing the translation process. One of the following must be checked.

☐ The consent documents and other relevant study materials will be translated by a certified translator.

☐ A non-certified translator will translate the consent documents and other relevant study materials and another individual will confirm the translation is accurate and appropriate. → *If selected, describe the translator's qualifications in the text below:*

31b. Attest that translated study materials will reflect the final IRB-approved English versions of all study materials and will be provided to the IRB for approval prior to use with participants, when applicable.

It is recommended to first submit and receive IRB approval for English versions of study materials and then submit translations of the final approved versions to the IRB via modification after initial approval. (Note, if the IRB determines your study to be exempt, this modification will not be required. Your IRB approval letter will indicate if the study is exempt.)

If translated versions are provided at the same time as English versions, please be sure any changes required by the IRB during review are reflected in both English and translated versions.

This box must be checked.

☐ Confirm

32. Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form. Template language for these disclosures is provided within our Consent Form Templates, available in the UTRMS-IRB Library.

☐ It is reasonable that researchers could discover or suspect child or elder abuse.
Add appropriate disclosure in consent form(s).

☐ It is reasonable that researchers could learn of an incident that could require reporting under Title IX.
Add appropriate disclosure in consent form(s). See Title IX and Research Guidance for more information on this requirement.

☒ It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition. → *answer the following:*

32a. Articulate methods for addressing and reporting incidental findings, if applicable.

If results will not be shared, provide a justification for why this will not occur. Ensure appropriate information is in consent form(s), as applicable. If the study involves genetic testing that could result in relevant findings, this should be addressed in item 11d and that response can be referenced below.

If incidental findings or other information of medical interest is discovered during a participant's enrollment, the participant will receive an MFM consultation, and any referrals deemed appropriate by the Principal Investigator and/or the co-Is.

32b. If research will be conducted at the UT Biomedical Imaging Center (BIC), check the box below to attest that researchers will comply with BIC requirements for reporting incidental findings, as outlined in the BIC Wiki. *Ensure appropriate language is included in all relevant consent forms. As a reminder, research conducted at the BIC is required to comply with all BIC policies/requirements. This can be left blank if not applicable (i.e. no research activities at the BIC).*

☐ Confirm

Compensation & Costs

33. Will subjects receive any compensation for their participation in the research?

See P&P section 4.8 for guidance on compensation.

☐ No → *skip to item 34*

☒ Yes

33a. Specify the type/total amount of compensation that will be provided to each participant:

$200 worth of gift cards:
Participants will receive a $100 electronic Tango gift card sent to their personal email after the second GAD-7 survey is completed within UT REDCap. This occurs after approximately 4 weeks of recordings USING the Womb Watch app. Participants will receive their final $100 electronic Tango gift card to their personal email upon completion of the final GAD-7 and the Usability survey, to be done within 7 days of delivery. The schedule for payments and other touch points for participants is included under Additional Documents. Participants will not be eligible for the full $200 compensation if they exit the study prior to completion.

33b. Indicate the type(s) of compensation offered: *Select all that apply*

☐ Cash ☐ ClinCard

☐ Check ☒ Tango Card

☐ Gift Card ☐ Course Credit

☐ Other, describe in the text box below:

33c. Will monetary payments be pro-rated so that participants who are unable to complete the research may still receive some part of payment? *(e.g. hourly rate, split across multiple study sessions, payment per activity completed, etc.)*

It is recommended that payment be prorated for the time of participation in the study rather than delayed until study completion, as making payment contingent on completing multiple sessions could unduly influence a subject's decision to exercise their right to withdraw at any time. It is acceptable, with an appropriate justification, to offer an additional incentive or completion bonus to subjects that complete all study activities, provided the incentive is not so large as to unduly influence subjects to stay in a study when they otherwise would have withdrawn.

☐ No → *skip to item 34*

☒ Yes → *describe the proration schedule in the text box below*:

Gift card dispersal is outlined in section 33a.

34. Costs

One of the following must be checked:

☐ Participants will have no costs associated with this study → *skip to item 35*

☒ Participants will have the following costs associated with this study:

- ☐ Standard of care procedures contributing to study data
- ☐ Research procedures/services not associated with standard of care
- ☐ Administration of drugs/devices
- ☐ Study drugs or devices
- ☒ Transportation and parking
- ☒ Other, describe below:

Participants must have functioning smartphone and access to the internet to upload app data to TACC. Routine cell phone/internet costs will be incurred.

Benefits

35. Benefits to Society

Describe the scientific and societal benefit(s) below.

Pregnant people with access to smartphones would potentially benefit from an app that provides reassurance that their fetus is doing well. In cases where the fetus is not doing well, they have the objective information to provide to their prenatal providers when reporting it. Ultimately, the goal of this app would be to create a personalized profile of fetal movement that could predict impending fetal compromise and prevent stillbirth.

36. Potential Direct Benefits to Participants

Click on the applicable check box. One of the following must be checked.

☒ There is no anticipated direct benefit to participants.

☐ There are anticipated benefits to participants. → *Describe potential direct benefits to participants below. Note that compensation (addressed in previous section) is not considered a "benefit" of research participation:*

37. Alternatives to Participation in this Study

Provide a description of any alternative procedures or treatments that might be advantageous to the subjects. For example, earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or standard clinical treatment from a health care provider instead of participating in research with an experimental drug or intervention, etc.

Routine obstetrical care.

Risks & Discomforts

38. Describe <u>all</u> reasonably foreseeable risks and discomforts associated with each activity in this research:

Transparency about all risks/discomforts, even those that are minimal, increases participant trust in the research enterprise and helps to prevent unanticipated problems or complaints. It is rarely acceptable to state there are "no risks." However, you are encouraged to provide your evaluation of the probability and magnitude of potential risks listed.

Categories of possible risks to consider may include (but are not limited to) the following:

- ***Physical** (e.g. bodily harms or discomforts, side effects. Consider any foreseeable discomforts, irritations, reactions, etc. that can result from equipment participants will use or interact with for the research);*
- ***Psychological/emotional** (e.g. boredom or mental fatigue, discomfort answering questions or providing personal information, embarrassment or self-consciousness during study procedures/interventions, learning unpleasant information about oneself or others, etc.);*
- ***Social or legal** (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.);*
- ***Financial or economic** (e.g. impacts on income, employability, or insurability, loss of services, etc.);*
- ***Research Design-specific risks** (e.g. unforeseeable risks of experimental procedures, disappointment with randomization outcomes, washout risks, placebo effects, withholding or delaying care/services, deception, etc.).*

***General loss of privacy/confidentiality** is an assumed, foreseeable risk that applies to all studies as data breaches or other errors of this nature are not uncommon. This general risk does not need to be reiterated below, but if there are more specific privacy/confidentiality risks associated with the research, these can be described. All foreseeable risks/discomforts must also be outlined in the consent form(s).*

Possible loss of privacy/confidentiality to participants and non-participants who are within recording range of app during use.

Participants may experience slight discomfort from holding the smartphone on their abdomen during the recording for 15 minutes daily.

Participants might become more anxious when provided with fetal movement analysis within the app.

Participants may seek out or delay their care based on the results provided from the app.

39. Describe how each risk listed above is mitigated/minimized.

General privacy and confidentiality protections do not need to be outlined here as these are covered in their own section below. Mitigation strategies for all other risks/discomforts described above should be outlined. Risk mitigation should also be outlined in the consent form(s), when applicable.

All data will be stored in HIPAA-compliant and password-protected storage space, UT Dell Med REDCap. To help mitigate privacy risk for participants and non-participants during app audio recording, participants will be informed during consent that the smartphone will record more than just the fetal movement sounds and that they should record in a quiet space with minimal conversations. This will be reinforced during the two-week check-ins with participants. The app will be able to record all audible sounds in addition to the fetal movement. Participants will have the option to delete and re-record if their recording session is interrupted. All app usage data transmitted to TACC from the app will be anonymized using an assigned study number. Audio files will only be analyzed at the frequency associated with fetal movement.

The study team will inform participants during consent and regular check-ins, to adjust their position if they experience any discomfort related to holding the smartphone in place. One suggestion might be that they use pillows for support while recording or switch hands as needed.

The study team will be reviewing GAD-7 surveys to ensure participants are not becoming overwhelmed by anxious feelings as interpreted by their GAD-7 score. If a participant is feeling more anxious, the study team will refer them to their provider for behavioral health resources as needed. The purpose of the GAD-7 surveys is to collect data on the participants' well-being while enrolled in the Womb Watch Study.

To address the concern over participants seeking out care based on the app results, the study team has included language, within the consent and within the app itself, to clarify that the results are not diagnostic and experimental only. If a participant has any concerns over fetal movement, they are advised to contact their healthcare provider. The PI and Co-I's have also opted to provide their direct cell phone numbers, listed under question 1 in the FAQs, found within the app as well as a "Contact" menu at the top left portion of the app screen. Their contact information is also on the consent.

40. Early Withdrawal

*Are there any planned or anticipated conditions under which a participant will be withdrawn from the study without their consent, **and/or** any safety issues for participants who choose to withdraw early? Be sure your response aligns with any information about withdrawal included in the consent form(s):*

☐ No → *skip to item 41*
☒ Yes → *answer the following:*

40a. List the criteria for withdrawing individual participants from the study:
Examples may include, but are not limited to, safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor, etc.

Participants may be asked to withdraw due to loss of eligibility/loss of pregnancy/inability to comply with the protocol.

40b. If applicable, describe any necessary procedures for ensuring the safety of a participant who withdraws/has been withdrawn early.

41. Data Safety Monitoring

Studies involving investigational drugs or devices are generally required to at least have a data safety management plan (DSMP), regardless of risk level. Studies that involve greater than minimal risk are strongly recommended to have a DSMP, and the IRB may require this in certain circumstances (e.g. if there is a known risk with expected frequency, etc.). Some studies, particularly those that are greater than minimal risk and involve sponsors or federal funding, may have a data safety monitoring board or committee that oversees ongoing safety reviews.

Otherwise, most minimal risk studies do not require a data safety plan or board, though sponsors or the IRB may require this under certain circumstances.

For additional information and reporting requirements regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.

After reviewing the information above, one of the following must be checked:

☒ This study does not involve a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB). → *skip to item 43*

☐ This study has an internal plan to monitor data for safety (Data Safety Monitoring Plan (DSMP)).

☐ This study has a Data Safety Monitoring Board or Committee (DSMB/C).

42. Data Safety Monitoring (Details) *select all that apply*

☐ This study has a DSMP document or DSMB charter describing safety monitoring details (including the list of board members for DSMBs) uploaded to UTRMS → *if all details below are covered in the uploaded document, skip to item 44*

☐ Details of the DSMP/DSMB processes are provided below:

42a. Describe the safety information that will be collected and reviewed for safety monitoring.

This description should include the following details:

- *the type(s) of information that will be collected to monitor individual participant safety*
- *any additional cumulative data that will be collected to monitor overall study safety (if different from what is obtained for participant monitoring)*
- *the schedule and frequency of safety data collection*

42b. Describe the data safety monitoring review process.

This description should include the following details:

- *Who will be responsible for reviewing safety data and identifying safety concerns?*
- *How frequently will safety data be reviewed by the responsible person(s)/board?*

42c. Describe any pre-specified safety threshold or criteria that would trigger immediate suspension of the study, if applicable.

Privacy & Confidentiality

43. Participant Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. Privacy protections apply to people, while confidentiality protections (addressed in the next item), apply to data.

In this section, describe how the study team will protect participants' privacy throughout all phases of the research, including during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data. For example, consider the locations where you will approach and question participants, the locations where data will be viewed/analyzed, how data collection procedures will limit the amount of sensitive or invasive data collected to only what is necessary to answer the research questions, how participants will be described in publications/presentations, etc.

The study team will protect participants' privacy from the initial recruitment, to recording in the Womb Watch app, to dissemination of data and in publication. During recruitment, if a participant chooses to scan the QR code on the study flyer, they will be directed to a Dell Med REDCap Womb Watch recruitment tool to complete a short survey of interest. Study coordinators will also exercise their use of the partial HIPAA waiver to screen for qualifying patients and approach them in clinic, in a private setting, to introduce them to the study, provide a flyer and review the consent form. For enrollment, participants will be asked to schedule a 15-30 minute screening/enrollment visit with a study coordinator. The study team will take care to review the ICF and data procedures in a private setting. All Womb Watch app recordings are secure within the TACC mainframe and in UT WombWatch Pilot Study Enrolled REDCap. Participants will be informed during consent that the recordings should take place in a private, quiet setting and that anything captured by the phone recording that is not related to fetal movements will not be analyzed. All data analysis will be anonymized for privacy and confidentiality. This applies to the fetal movement data analysis for feasibility and also for any publications related to this data.

44. Data Confidentiality and Security Plan

Confidentiality refers to the way private information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, audo/video recordings, photographs, etc.) are protected from unauthorized access.

In this section, describe whether any participant identifiers (e.g. names, contact info, etc.) will be collected during the conduct of the research and if identifiers will be linked to research data for <u>any</u> period of time. Include the following, as applicable:

- *If identifiers will be used for contact or compensation purposes only, and will <u>never</u> be linked to specific responses, describe the methods used to accomplish this.*
- *If identifiers will be coded/pseudonymized to protect confidentiality, describe whether or not a code key will be created linking study IDs/pseudonyms to identifiers, who will have access to the key, and how it will be stored separately from the research data.*
- *If the study involves collection of audio/video recordings or photographs, describe any plans for protecting identifiable content (e.g., avoidance of recording identifiable information/full faces, redacting recordings or transcripts, etc.).*

All data will be stored in HIPAA-compliant and password-protected storage space, UT Dell Med REDCap.. Participating site study teams have been added to the Dell Med REDCap as users to input data and will be adding data directly to Dell Med REDCap. No data storage will take place at participating sites. All app usage data captured by TACC will be anonymized. Patient confidentiality and privacy is strictly held in trust by the participating Investigators and their staff. This confidentiality is extended to cover the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in confidence. No information concerning the study or the data will be released to any unauthorized third party. All research activities will be conducted in a private setting. The participants' contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the IRB, institutional policies and regulatory authority requirements. Individual participants and their research data will be identified by a unique study identification number.
Identifiers will be coded to protect confidentiality. Participants will be de-identified using a participant number and all data will be stored in the HIPAA-compliant password-protected storage space, UT Dell Medical School REDCap. All audio recordings taken via the Womb Watch app will be

stored on TACC's mainframe computer which is HIPAA compliant. Deidentified, anonymized recordings will be kept indefinitely on the basis of data analysis and public interest/scientific research. Data recordings continually refine the AI Machine Learning model. HIPAA identifiers will be removed from the data after 6 years.

45. Does the study have (or do you plan to apply for) a Certificate of Confidentiality from the National Institute of Health (NIH)?

☒ No

☐ Yes - NIH has issued a Certificate of Confidentiality for this study.
Ensure CoC language is included in the consent form(s).

☐ Yes - a Certificate of Confidentiality has not been obtained, but there are plans to apply for one.
Apply for a CoC for non-NIH funded research here: NIH Certificate of Confidentiality System. Once CoC is granted by NIH, you must submit a modification to add CoC language to the consent form and ensure a copy of the CoC approval (only for non-NIH funded research) is uploaded to UTRMS-IRB.

46. Electronic Materials - Storage and Access

In this section, select all methods that will be used to protect the confidentiality of research data.
At least one of the following must be checked, select all that apply.

☒ Electronic data and records will be stored on a password-protected cloud service that is currently listed as approved on the UT Information Security Office (ISO) platform matrix. Access to data will be limited only to individuals who need access for purposes related directly to this research study. *(Strongly recommended)*
The matrix of current UT Austin ISO approved platforms is available here: https://security.utexas.edu/iso-policies/cloud-services/decision-matrix

☐ Electronic data and records will be stored on a third-party cloud service/platform that is not currently approved for research data storage by UT Austin's Information Security Office (ISO) and requires local ISO approval. → *If this box is checked, the study team must obtain security clearance from UT Austin ISO (or Dell Med IT, if applicable) approving use of this platform to store research data for this study. UT IRB approval cannot be granted until documentation of ISO/IT approval has been uploaded to the study in UTRMS under "Other Attachments." To avoid delaying approval, consider selecting a different option for storing data, if possible.*

☐ Other method(s) of storing and limiting access to electronic data and records, describe in the text box below:
Examples might include use of a platform hosted and approved by a collaborating institution or sponsor for this research, use of non-cloud-based electronic storage methods (e.g. hard drive), etc.:

47. Physical Materials – Storage and Access

One of the following must be checked.

☒ Physical data/records/specimens *(e.g. signed research consent forms, paper surveys/notes, physical recordings, samples etc.)* will be stored in a secure location with access limited only to individuals who need access for purposes related directly to this research study.

☐ N/A – no physical materials

48. Research Records Retention Attestation

Confirm that research records will be maintained in compliance with all relevant records retention policies.

UT Austin's research record retention policy requires that data and copies of relevant study documents (e.g. consent forms, protocol, recruitment materials, etc.) be maintained for at least 3 years from completion of the research project. Note that researchers are NOT required to maintain identifiers linked to data for 3 years. To protect confidentiality, identifiers can be unlinked from study data and destroyed as soon as feasible (described in the next item). UT Austin's records retention policies are available here: https://records.utexas.edu/utrrs

Some research may be subject to other retention policies that require longer retention periods and retention of other specific data or materials (e.g. collaborating institutions, funding agencies or sponsors, FDA, HIPAA, etc.). For example, studies that involve use of protected health information (PHI) covered by HIPAA must retain all relevant records for at least 6 years.

Check the box below to acknowledge the above information and confirm the study team will comply with UT Austin's policy as well as any other records retention policies that apply to this research.

This box must be checked.

☒ Confirm

49. Destruction of Identifiable Information

One of the following must be checked. Be sure your response accounts for all data, records, audio/video recordings, etc. collected for the research.

☐ No identifiable information is recorded at any point in this research.

☒ Identifiable information will be destroyed. → *Specify at what point in the research process identifiable information collected about participants will be destroyed. At least one of the following must be checked:*

- ☐ Upon completion of procedures requiring use of identifiers *(i.e. compensation, data linkage, etc.)*
- ☐ After all data collection/cleaning/transcription is complete
- ☒ At the time of study closure/once study is complete
- ☐ Other, describe below:

☐ Identifiable information will not be destroyed.

If checked, explain the rationale for retaining identifiers indefinitely and specify if identifiers will remain linked to research data (either directly or indirectly via a code key).

Data Sharing & Future Use

50. Data Sharing and Future Use

Check the box below that best describes your plans for use and sharing of data beyond the scope of the current research. You are strongly encouraged to consider the broadest possible future plans you might have. ***One of the following must be checked.***

☐ There are no plans to use or share data/specimens for other research purposes not related to this study. → *skip to item 52*

☒ Data/specimens may be shared with other researchers or banked (by this study team or other researchers) for future research purposes not related to the current research. → *address the following:*

50a. Select which data sharing plans/future uses apply:

"Coded" refers to data that is indirectly identifiable via a code key that links study ID#s back to participant identifiers. Ensure this aligns with the description of future use in the consent form(s), when applicable.

☒ Anonymized data/specimens may be shared or banked for future research → *skip to item 52*

☐ Coded data/specimens may be shared or banked for future research → *complete section 51*

☐ Identifiable data/specimens may be shared or banked for future research → *complete section 51*

51. Data Registry/Specimen Repository (Details)

Select all that apply.

☐ Contributing data/specimens to an existing registry/repository → *describe this registry below; if this registry is maintained by UT researchers, provide the IRB Study ID# and/or the registry name and Principal Investigator responsible for the registry:*

☐ Creating a new registry/repository → *complete the following:*

51a. Describe the intended purpose and target area(s) for this registry:

51b. Describe any options that will be provided to participants to stipulate future use of their data/specimens. If participants will be given the option to be contacted regarding future uses, describe the procedure(s) for this contact.

Be sure to include all options and stipulations in the consent form(s). If no stipulations or future contact will be offered, explain this below.

51c. Who will be allowed access to registry data/specimens?

☐ Only the PI of this study and/or other members of the current study team → *skip to item 52*

☐ Other researchers will be able to request data/specimens from the registry → *below, describe how other researchers will be able to request data/specimens from the registry, what criteria will be used to approve such requests (e.g., IRB approval, application process), and what methods will be used to release data/specimens to other researchers securely:*

Conflicts of Interest

Please confirm that all research personnel who meet the definition of "covered individuals" are designated as such in the Local Study Team Members section of the SmartForm application in UTRMS-IRB.

52. Financial Conflicts of Interest

Financial interest includes utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project. Additional guidance on financial conflicts of interest is available on the COI website.

One of the following must be checked.

☐ To the best of your knowledge, no one on the study team has a financial interest related to this study.

☒ The PI and/or other covered individual(s) has/have a financial interest related to this study.

If so, please provide the name(s) of the covered individuals involved, and briefly describe the interest:

Drs Moise and Gaither are co-inventors of this app. A provisional patent has been sent to the U.S. Patent Office .

53. Non-financial Conflicts of Interest

Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity,
- equity or business ownership in a company that has yet to make a profit and is related to this project,
- conflict of time/effort,
- personal and professional relationships/affiliations,
- personal beliefs/feelings impacting ability to conduct the study without bias,
- any other factors that could create bias in the study

One of the following must be checked.

☒ To the best of your knowledge, no one on the study team has non-financial interest related to this study.

☐ The PI and/or other covered individual(s) has/have a non-financial interest related to this study.

If so, please provide the name(s) of the covered individuals involved, and briefly describe the interest: