The Journey Pregnancy App Study
Frequently Asked Questions

Emagine Solutions Technology

Central Phoenix Obstetrics and Gynecology

UC San Diego School of Medicine

National Science Foundation

What is this study about?
Researchers want to find out more about an investigational software called The Journey Pregnancy APP (here after called "study software").
and determine if the information entered by users can be used to recognize the emergence of a pregnancy condition called Preeclampsia. An investigational software is a software that is being evaluated. **The Journey** is a software application for pregnant patients to log their blood pressure, weight etc. and track their symptoms, cravings, and aversions so that they can have a record of their pregnancy. This software is informational and is not intended to diagnose or treat any medical condition.
The main purpose of the research study is for the sponsor **EMAGINE SOLUTIONS TECHNOLOGY** to gather data to analyze the accuracy of predictive algorithms they're developing to detect preeclampsia, as well as to gather feedback on the usability of the beta version of the software by patients who are currently experiencing a pregnancy. It is planned that about **150** people will be in this study.

How does the Journey pregnancy app work?
This system works as a type of "personal health diary" for pregnancy. Participants download the app The Journey Pregnancy and set up their account by entering information for the pregnancy, such as expected date of delivery. After setting up their account and answering the initial questions, participants will be asked to document their blood pressure, weight, etc., in the app daily. The team will track the data remotely. The software is not intended to treat or diagnose – it is informational only.

Who is paying for this study?
This study is funded by the National Science Foundation. A company called Emagine Solutions Technology, the sponsor of the study and manufacturer of the study software. Members of the study staff are employees or executives or advisors of the sponsor. If you have concerns about this employment, ask the study researcher listed at the end of this document for more information. Courtney Williams, the principal investigator for this research, is a part owner of the sponsor company. Please feel free to ask any questions you may have about this relationship.

Will I be compensated for participating in this study?
No, you will not be compensated for any time inconvenience related to your participation in this study. Participation is on a purely voluntary basis.

Will it cost anything to be in this study?
No. You will get The Journey Pregnancy app free of charge. Neither you nor your health-care payer/insurer nor your doctor will be billed for costs of the study software or the costs of administering the study software.

How long is the study?
If you want to be in this study and the study researcher says you can be in the study, you will be asked to input data daily during your pregnancy and the postpartum period. After the study period, you can continue to use the app even for another pregnancy, but the study team will no longer be tracking your data.

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What will happen during this study?
If you choose to be in the study a member of the research team will give you instructions about how to download the study software. You will be asked to use the software application each day for the remainder of your pregnancy and postpartum period to log your blood pressure, weight, etc. You may also upload pictures if desired. If you would like more information about the functions of the software, ask the study researcher or study staff by sending an email to (questions@emaginest.com). This technology is not a substitute for treatment, nor will it serve to diagnose any condition.

As a part of the study, you will be asked to take a 5–10-minute online survey about your user experience with the software before day 1 and on or after the last day of the research period. The feedback you provide will allow the study researcher to judge the quality of the software, how easy the app is to use, and how best to analyze data from the study software.

There will be no diagnosis or diagnosis-associated treatment done with the study software.

While you are in the study, it is important that you:

- ☐ Follow the instructions you are given.
- ☐ Tell the study researcher or study staff if you are uncomfortable with the beta software testing.
- ☐ Tell the study researcher or study staff if you want to stop being in the study at anytime.

How will participant information be kept confidential?
Your confidentiality will be protected as required by law and according to any policies the study center or sponsor may have. The type of information that will be collected relates to pregnancy progress, such as symptoms experienced, vitals entered, cravings and aversions experienced. When you enter your information into the software, a confidential identification number will replace your name and any other personally identifiable information on the study data and forms. The link between the confidential identification number and your name will be kept by the study center and the sponsor. Your data will be saved securely per HIPAA guidelines. The study sponsor will use Amazon DynamoDB in Amazon Web Service (AWS). This database ensures that data containing protected Health Information uses endpoints that accept encrypted transport. Data stored in the underlying storage is encrypted consistent with best practices and NIST Guidance. Your data will be automatically deleted 90 days after the completion of the research study.

The sponsor is not collecting any of your personal health information or medical records outside of what is collected for this study. Be aware that your study records (your signed consent form and de-identified information) will be shared and copied as needed for the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Who will use and share information about my being in this study?
This section explains who will use and share your personal health information if you agree to be in this study. If you do not sign this form, you cannot be in the study.

During the study, the study researcher and study staff will use, collect, and share health information about you (your "study records"). Your study records will include only information that the study researcher needs to do the study, such as your signed consent form, confidential identification number, de-identified data, surveys, and research report form.

Your health information will be used or shared when required by law with these people for the following purposes:

- ☐ The study researcher and study staff to conduct the research described in this consent form
- ☐ The sponsor, EMAGINE SOLUTIONS TECHNOLOGY, the developer of this technology to improve the interface, usability and function, and predictive algorithms for the software
- ☐ Others required by law to review the quality and safety of research including: the Food and Drug Administration (FDA), other government agencies in the United States and other countries.
- ☐ The Institutional Review Board (IRB) who oversees the research to protect the rights of subjects

There are federal, state, and local laws that require the study researcher protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the study researcher shares your study records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your study records with other people who do not have to protect the privacy of your records. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. No public presentation about the research described in this consent will reveal your identity without permission from you.

You have the right to see and copy your study records related to this research. You will not be able to see or copy some of your records until after all participants finish the study. You are free to share the information you record on your app your doctor or health care provider at any time.

You can cancel this authorization to use and share your study records at any time. If you want to cancel your authorization, write a letter with your request to the study researcher at the address on page one of this document. If you cancel your authorization, you will not be able to continue in the study. Even if you cancel your authorization and leave the study early, the study researcher and study staff will still be able to use and share your records that they have already collected as described above.

Once you consent to be a part of this study, your authorization to use and share your records expires in 5 years from the date of your signature on this consent. You will receive a signed copy of this form upon request.

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What if I get hurt or sick while I am in this study?
You do not give up any of your legal rights or release the Sponsor, the principal investigator, the study staff, or study site from liability for mistakes or intentional misconduct by signing this form.

During the study, if you experience any medical problems, please contact your regular doctor to make sure you receive needed medical care. This app CANNOT transmit information to a health care provider. If you are able, please notifying the research staff if your illness will prevent you from completing the entire study period.

Although this app collects data related to your health, it is not related to your regular medical care. The research team has no way of reaching your healthcare provider on a regular basis or in an emergency. You may receive alerts about the data you put into the app directing you to seek further medical care. These alerts are based on the best clinical information available at the time of development, but it may or may not be relevant to you when you see them. These alerts are meant to educate and are NOT medical advice. Please consult your own health care provider and follow their recommendations for any health care concerns. This app is NOT A SUBSTITUTE FOR REGULAR PRENATAL CARE.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to EMAGINE SOLUTIONS TECHNOLOGY at 9040 S. Rita Road, Suite 1270, Tucson, AZ 85747.

Will I receive any new information during the study?
If the study researcher or study staff learns any new information that might change your mind about continuing in the study, the study researcher or study staff will tell you about it.

Your participation in this study is voluntary. You can decide not to be in the study, and you can change your mind about being in the study at any time without any penalty or loss of benefits to which you are otherwise entitled. If you want to stop being in the study, tell the study researcher or study staff.

The study researcher or study staff or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- ☐ The study researcher or study staff believes it is best for you to stop being in the study
- ☐ You do not follow directions about the study
- ☐ The sponsor stops the study for any reason

If you leave the study, the study staff will still be able to use your information that they have already collected.

Who can I talk to if I have questions about this study?
You can ask questions about the study at any time. You can call or email the study researcher or study staff at any time if you have any concerns or complaints. You should call the study researcher or study staff at the phone number listed on page one of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.

- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

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Will being in this study help participants?
Being in this study will not help you directly during your pregnancy. Some people may find a benefit in having one place to record your information in pregnancy. Information from this study will help the sponsor gather important feedback from participants on the quality of the study software that may help people in the future.

Are participants paid to be in this study?
You will not be paid for any time or inconvenience related to your participation in this study. Participation is on a purely voluntary basis. You will be given a gift card valued at $10 at the beginning of the study and a second gift card valued at $15 as a thank you at the end of the study.

Are there risks to me if I am in this study?
This study will not involve any physical risk to you. Your participation is completely voluntary. If you have any questions about your participation at any time during the study, please tell the study researcher or the study staff (questions@emaginest). This app is a software program. With any software program there is a small risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study researcher or study staff if you would like to know more about how your information will be protected while you are in this study.com).

Are there risks if I am pregnant during the study?
No, there are no known physical risks to you or your pregnancy.