

## CONSENT TO PARTICIPATE IN RESEARCH

### ***Global Women's Health Outcomes Study***

#### **Introduction**

My name is *Madelena Ng*. I am a *graduate student* at the University of California, Berkeley, working with my faculty advisor, *Professor Denise Herd*, in the School/Department of *Public Health*. I am planning to conduct a research study, which I invite you to take part in.

You are being invited to participate in this study because you are a woman who is 18 years old or older, understands English, and has an iPhone.

#### **Purpose**

The purpose of this study is to *understand (1) how women participate in and experience a digital research study and (2) how blockchain technology can be used to address persisting participation challenges in digital research*. The *Global Women's Health Outcome Study (GWHOS)* is a prototype digital study that focuses on women's reproductive health. Participants complete GWHOS research activities and donate digital health data electronically (i.e., exclusively via their smartphones) through the Bitmark app. Participants donate data to further understanding about reproductive health patterns (e.g., irregular menstruation) and help explore the concept of data ownership in digital research.

*Bitmark Inc.* is a partner whose role is to provide the technical infrastructure for the GWHOS prototype. Bitmark is a property system built on a public blockchain—a digitized, decentralized, public ledger for all transactions. Bitmark records property titles, known as "bitmarks," for digital data on its blockchain. The system allows participants to donate their "bitmarked" digital data pseudonymously to researchers. The partnership enabled the creation of a proof of concept prototype for digital research participation and systematic usability evaluation.

*The proposed research activities are purely exploratory with no prior hypothesis.*

#### **Procedures**

If you agree to be in this study, you will be asked to do the following:

Specify which data from your Health ([www.apple.com/ios/health/](http://www.apple.com/ios/health/)) app you would like to donate to the study. Donated data will be consolidated from your smartphone and encrypted prior to transferring to researchers.

Data sources the research team are interested in receiving include:

- Basal Body Temperature
- Cervical Mucous Quality
- Exercise Time
- Flights Climbed
- Intermenstrual Bleeding (Spotting)
- Menstrual Flow
- Mindful Minutes
- Ovulation Test Result
- Sexual Activity
- Sleep Analysis
- Step Count
- Walking/Running Distance

After this step, you can decide to complete a one-time intake survey activity electronically through the app. The study recommends entering the app weekly to manually authorize data donations of accrued data. You will receive notifications/reminders throughout the study period reminding you to donate. After the study period of 100 days, you will be prompted to complete an exit survey electronically through the app. You may also be recruited to participate in an audio-recorded exit interview, which is an optional study activity.

### **Before you begin the main part of the study...**

You will need to have the following screening tests/procedures to find out if you can be in the main part of the study.

- Download the Bitmark app and create an account (~ 2 min)
- Access the "Global Women's Health Outcome Study" (~ 1 min)
- Review the participant and data requirements to determine eligibility (~ 2 min)
- Complete informed consent on-boarding section prior to giving consent (~ 10 min)

### **During the main part of the study...**

If the screening procedure shows that you can be in the main part of the study and you choose to continue, this is what will happen next:

- *Specify which Health app data sources you want to donate to the study (~ 5 min)*
- *Complete a one-time intake survey for donation (~ 5 min)*
- *Enable push notifications/reminders (~ 1 min)*
- *Enter the app weekly to manually authorize donations of accrued data to researchers (~2 min each)*
- *Complete exit survey (~ 5 min)*
- *Participate in an in-depth exit interview (optional; audio-recorded, ~ 45 min)*

**Study time:** Your study participation will take a total of *approximately 3 minutes per week for up to 100 days*. If you choose to participate in the exit interview, that will take a total of *approximately 45 minutes*.

**Study location:** All study procedures will take place *remotely through the Bitmark app unless required otherwise*.

## **Benefits**

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help *researchers better understand the application and impact of blockchain technology for a women's health-focused digital study*.

## **Risks/Discomforts**

- Some of the personal health data requested may make you uncomfortable. You can simply choose to not donate specific data at any time.
- For the optional exit interview, there may exist a risk of discomfort due to subject matter. You can choose to decline to answer any questions or stop the interview at any time.
- **Breach of confidentiality:** As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. Participants are pseudonymous (they have a "public key" made up of a long string of numbers and letters) when they donate their encrypted data to the researcher. No personal identifiable information is collected. It would be very difficult to connect decrypted donated data back to a specific person.

- The researcher is also the only person with a key to decrypt the donated data. This minimizes the possibility of a data breach. There is a small possibility that the researcher's key (also a long string of numbers and letters) is copied and used to decrypt the donated data. Thus, it is recommended that the key is written down rather than stored on a digital device.

## Confidentiality

- Your study data will be handled as confidentially as possible. No personal identifiable information will be collected. Each of your data donations will be transferred anonymously and encrypted to researchers. Data will be merged by researchers based on the participant's unique public key.
- To minimize the risks to confidentiality, your data will be encrypted in transit, stored in password protected computers, and only accessible by the study team.
- For the optional exit interview, interviewee responses will be audio-recorded. Audio recordings are generally considered identifiable information. In the event that we cannot mask the distinguishing features in the recording, we will not link your interview or any other identifiable information to your donated data. We will also redact any identifiable information that appear in the transcripts. Audio recordings for the optional exit interview will be deleted after transcription and data analysis.

## Costs of Study Participation

You may incur small data charges from receiving push notifications. This happens when study push notifications are allowed to come through via using cellular data and not restricted to Wi-Fi. You can ensure that data charges associated with the study are minimized by updating your cellular data settings ("Settings>Cellular>Data Donation").

## Compensation

You will not be paid for taking part in this study.

*This study involves only minimal risk of harm to subjects.*

## Rights

**Participation in research is completely voluntary.** You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

## Questions

If you have any questions or concerns about this study, you may contact *Madelena Ng* at [madelena.ng@berkeley.edu](mailto:madelena.ng@berkeley.edu). A member of the study team will respond to provide support and troubleshoot your request.

If you have any questions or concerns about your rights and treatment as a research subject, you may contact the office of UC Berkeley's Committee for the Protection of Human Subjects, at 510-642-7461 or [subjects@berkeley.edu](mailto:subjects@berkeley.edu).

## CONSENT

This consent form is accessible on the Bitmark app at any time.

If you wish to participate in this study, please click "AGREE" in the Bitmark app to proceed.