

# Driver Alcohol Detection System for Safety: Field Operational Test

## Eligibility/Demographic Questionnaire

---

Submitted by:



Technologies, Inc.

KEA Technologies, Inc.  
400 Donald Lynch Blvd, Suite 102  
Marlborough, MA 01752  
(508) 658 - 9416

### **Principal Investigator**

Kelly Ozdemir, PhD.  
Director of Applied Sciences  
KEA Technologies, Inc.  
400 Donald Lynch Blvd, Suite 102  
Marlborough, MA 01752  
(508) 658 - 9425  
[Kelly.Ozdemir@keatechinc.com](mailto:Kelly.Ozdemir@keatechinc.com)

*Paperwork Reduction Act Statement: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2127-0734. The purpose of the information collection is to collect information to provide a greater understanding of the performance of both breath- and touch-based sensors with actual dosed passengers using the technology under varying environmental conditions. The primary component of this information collection is the collection of sensor data during a Field Operational Test (FOT) involving human subjects; however, demographic information about participants and post-test information will be collected as well. The objectives of the FOT are to: (1) Determine the effectiveness of the DADSS sensors in a real-world driving environment; (2) Analyze DADSS breath- and touch-based sensors in real-world driving scenarios; and (3) Obtain technical data to further refine the DADSS Performance Specifications that will ultimately be used for system design and product development. We estimate that it will take approximately 30 minutes to one hour to complete the orientation and up to 5 hours to complete the FOT. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Room W45-205, Washington, DC, 20590.*

Hi may I speak to .....

**(Preface:)**

**Thank you for your interest in our research study. Is this a good time to talk? Would you be willing to answer questions about your health and medical history to find out if you might qualify for the study? Before I ask the first few questions, I would like to tell you a little more about who we are and what we do here. I work for a company called KEA Technologies where we are primarily trying to develop sensors that can detect alcohol levels through passive breath. Due to the nature of our research some of the questions might seem somewhat personal, and I want to let you know that at any point during this phone interview you are free to end the questioning and all of your information will be deleted from our records. I will be recording your answers in writing, but I will not collect any detailed contact information unless you qualify for the study and want to schedule an in- person visit. The risk of allowing us to record your name with your answers is a loss of confidentiality. We will take reasonable steps to protect the confidentiality of your information. May I begin?**

**Demographic**

1. How do you spell your first name?
2. What is the first initial of your last name?
3. What do you consider your race or ethnicity to be?
4. How old are you?
5. What was your biological sex at birth?
  
6. What do you consider your gender to be?

If non-binary, gender neutral, or other, ask for pronouns.

7. And when are you generally available during the work week?
8. What town/state do you live in?
9. Do you have a valid social security number?

**General Health Information**

1. How tall are you?
2. How much do you weigh approximately?
3. On a scale of Excellent, Very Good, Good, Fair, Poor... how would you describe your health?  
IF Fair/ Poor, why?
4. Have you ever had an illness more serious than a cold or flu? (something like pneumonia, mono, COVID-19, strep or something as serious as cancer; IF YES also ask about any possible complications)  
IF YES, about how long ago was that?  
What was the illness? If COVID-19:

What was the approximate date that you tested positive?  
What kind of test confirmed your positive result (PCR, antigen, antibody, or rapid)?

Do you have any of the following symptoms still: Shortness of breath, chest pain, fatigue, brain fog, muscle aches, etc.

5. Have you ever been hospitalized overnight or had surgery?  
IF YES, about how long ago was that?  
What was it for?
6. Are you currently taking any prescription medication?  
IF YES, what is it?  
What was it prescribed for?  
Dosage? Length of time on?
7. Do you have any allergies or adverse drug reactions?
8. Have you ever lost consciousness or had a concussion?  
IF YES, can you describe the injury?  
Did you see a doctor about it?  
What symptoms? Length?  
About how long did you lose consciousness?
9. Have you ever had migraines, seizures, or sleep disorders?  
IF YES, did you ever see a doctor about it?  
Were you prescribed any medications/ do you take any medications for it?
10. Have you ever had asthma?
11. Have you ever had heart problems or high blood pressure?
12. Have you ever been diagnosed with Raynaud's syndrome, ulcerative skin diseases, diabetes, or any auto-immune disorders  
IF YES, which disease(s)/disorders?  
Were you prescribed any medications/ do you take any medications for it?
13. Have you ever had hepatitis, jaundice, any blood diseases/disorders, or are you HIV-positive?
14. Have you received a COVID-19 vaccine?  
If YES, what brand and what was the approximate date of your first dose?  
If two-dose vaccine: what was the date you received your second dose?  
If haven't received it yet, what is the scheduled date of your second dose?

Could you provide proof of vaccination with a CDC vaccination card?

**IF FEMALE:**

1. Do you menstruate regularly?
2. Are you on any birth control?  
IF YES, what kind?  
IF IUD, what brand?

**Mental Health**

1. Have you ever seen a psychologist or counselor for any issues? (Which was it?)  
IF YES, about how long ago was that?  
What was going on at the time?

Were you put on any medications?  
IF YES, what medication were/are you on?  
What was it for?

Were you given any formal diagnoses?

### **Substance Use**

1. Do you smoke cigarettes?  
IF YES, how often do you smoke?
2. How many cigarettes do you smoke in a day?
3. How long has this been your pattern of smoking?
4. How old were you when you started smoking cigarettes daily?
5. Are you actively looking to cut down or quit your cigarette use?
6. Are you currently using any methods to cut down or quit such as a nicotine patch, gum, electronic cigarette, or any other method?
7. How many times a week do you drink alcoholic beverages?
8. On those occasions when you drink, about how many drinks do you have? (Clarify type)
9. How long has this been your pattern of use?
10. Was there ever a period of time in your life where you were drinking more heavily?  
How often were you drinking then?

**Now I'm going to ask you some questions about your history of drug use in order to determine whether you qualify for our study. I want to remind you that everything you tell me will be kept confidential.**

Have you ever used: marijuana, cocaine, ecstasy, stimulants/ speed (such as Adderall, Ritalin, crystal meth), PCP, LSD, mushrooms, mescaline, GHB, ketamine, sedatives/ downers (such as Ativan, Klonopin, or Xanax), pain killers recreationally (such as Vicodin, Percocet, or Oxy), opium, heroin, inhalants (such as nitrous oxide), or any other drug? (Specify if prescription if taken as directed)

1. When was the last time you used [drug]?
2. How often do you use [drug]? (Marijuana, add: can you estimate how much you use per week in ounces or grams?)
3. For how long has this been your pattern of use?
4. Are you actively looking to cut down or quit?
5. Has there ever been a time when you use [drug] more heavily?
6. How often were you using [drug] during this period of time?  
How much?
7. Have you ever been cited for driving while intoxicated?  
IF YES, when was then?
8. Do you feel like you've ever had a drug or alcohol problem?  
IF YES, what substance did you have a problem with?  
IF NO, has anyone close to you ever felt you had a drug or alcohol problem?
9. Do you have a family history of alcoholism?  
IF YES, who?
10. Do you have coffee, tea, soda, energy drinks, or any other form of caffeine on a daily basis?  
IF YES, what do you drink?

### **Availability**

1. Have you ever been in a medical research study before?  
IF YES, where was it?  
Is the study still going on?  
What was/is it for?
2. How did you find out about our research?
3. Do you have a car available to you?
4. Have you traveled internationally or out of state in the last two weeks?
5. Do you plan to travel internationally or out of state in the next month?

**Is the phone number I called you on the best to reach you?**

Ok. Those are all the questions that I have for you right now. What will happen now is that I'm going to review your information to see if you qualify for our research study. If you DO qualify for our research study, the research coordinator will get back to you within the next week. If you DO NOT hear from someone by then it means that you currently do not qualify for the research study/ any research studies.

Thank you for your time [name], have a good day.

**Leaving a message:**

Hi my name is [NAME] and this message is for [NAME]. I'm calling you about a research study you inquired about. You can give me a call back at my desk at--[EXT] between the hours of 8am and 4pm Monday through Friday. Again this message is for [NAME]. My name is [NAME] and I can be reached at--[EXT]. Thank you.