



**PHRONETIK INC  
OFFICE OF SPONSORED RESEARCH  
CONSENT TO BE PART OF A RESEARCH STUDY**

**1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY**

**Study title:**

**Principal Investigator:** [Name, credentials, institutional affiliation]

**Co-Investigator(s):** [Name, credentials, institutional affiliation] Delete if this does not apply.

**Study Sponsor:** [Name] Delete if this does not apply.

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study. If this document will be used to obtain parental permission for their child to participate in research, replace “you” with “your child” throughout.

The revised Common Rule requires a concise and focused description of the research project to be included at the beginning of the consent document. This section is required for complex research projects such as those involving multiple study procedures and those posing more than minimal risk to participants. If this does not apply to your project, delete Section 1.1 below.

**1.1 Key Information**

Things you should know:

- The purpose of the study is to [provide a brief, simple, non-technical description of the project].
- If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
- Risks or discomforts from this research include [briefly describe].
- The direct benefits of your participation are [description of potential direct benefits to participants – or state that there are no direct benefits].

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

**2. PURPOSE OF THIS STUDY**

Briefly, in one paragraph, explain in simple, non-technical language, the scientific reason for doing this study. Do not describe the details of the protocol here – protocol details should be described in Section 4 “Information about Study Participation.”

**3. WHO CAN PARTICIPATE IN THE STUDY**

**3.1 Who can take part in this study?** List important eligibility criteria (e.g., age, gender, language, health condition, etc.) in simple, non-technical language. Also, include a discussion of any important exclusion criteria, if applicable.



**3.2 How many people are expected to take part in this study?** This question is optional. Some participants may wish to know how many others will be taking part. Delete this section if you will not provide this information.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

### 4.1 What will happen to me in this study?

Explain in lay terms, typically in chronological order, what will happen to participants during the study. List all research/experimental procedures in this section. The following should always be included, if applicable:

- The location where research activities/procedures will take place
- Description of all research interactions/experimental activities or interventions
- Data collection procedures (surveys, interviews, audio-visual recording, observation, etc.)
- Identification of which procedures are standard and which are experimental
- Randomization procedures
- Use of medical records
- Linking of data collected or created as part of the research to other information, such as protected health information, administrative data such as from the U.S. Census or state agencies, or publicly available information
- For projects involving the collection of sensitive information or questions that might be upsetting, include examples of the types of questions asked or describe the sensitive topics involved.

**4.2 How much of my time will be needed to take part in this study?** Explain as needed, describing time in hours, number of interactions or study visits, and duration of the research. For example, “Participants will be asked to take one survey each month for a period of six months. Each survey is expected to take about one hour.” Be liberal in the estimation of how much time is required and ensure that it is consistent with what you have described in the eResearch application. If this is a longitudinal project, tell participants that you may contact them again in the future and provide the interval if known.

**4.2.1 When will my participation in the study be over?** Necessary only if not addressed in 4.2 above, otherwise delete this section.

### 4.3 If I decide not to take part in this study, what other options do I have?

For projects that involve an intervention that might improve a condition or disease, describe alternatives to participating in the research. These could include an intervention or treatment available outside the research context. Required only for studies that treat a condition or disease. Delete this section if not applicable.

There may be other ways of treating your condition if you do not want to be in this research study. Check with your health care provider to discuss other options.



## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

### 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Describe the known or expected risks of the study. These may be physical, psychological, legal or informational. Breach of confidentiality (i.e., informational risks) is a potential risk in all research that collects or maintains personally identifiable information and may be the only risk in some studies.

The researchers will try to minimize these risks by [describe what you will do to protect participants against risks.] For example, psychological risks could be mitigated by providing participants with counseling resources.

For projects that involve surveys/interviews/focus groups, include the statement: You do not have to answer any questions you do not want to answer.

For informational risks state: Because this study collects information about you, [one of the risks/the primary risk] of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

#### 5.1.1 What happens if I get hurt, become sick, or have other problems because of this research? For more than minimal risk projects only - delete section 5.1.1 for minimal risk projects (most projects reviewed by IRB do not require this section).

The researchers have taken steps to minimize the risks of this study. Please tell the researchers if you have any injuries or problems related to your participation in the study. For health-related research involving treatment, include: You should also tell your regular doctors. The Phronetik Office for Research may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

### 5.2 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. **or** You might benefit from being in the study [describe direct benefits]. Note: Compensation for research participation is not considered a benefit of the research. Information about compensation should be described in Section 7.

### 5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Include this section for health-related research involving an intervention, otherwise delete. Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

## 6. ENDING THE STUDY



### **6.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

## **7. FINANCIAL INFORMATION**

**7.1 Will I be paid or given anything for taking part in this study?** You will receive [type and total amount of compensation] for your participation in the study. Describe how compensation will be distributed if the participant withdraws from the research before the end of the study.

If compensation is more than \$100 in a calendar, the Phronetik accounting department requires that SSN and other information be collected for tax purposes. Insert the following: Because this study pays more than \$100 in a calendar year, the Phronetik accounting department will collect and safely store your name, address, social security number, and payment amount for tax reporting purposes. If you receive more than \$600 in payments in a calendar year, this information will be sent to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a Phronetik employee, your research payments are tracked separately and are not included as part of your payroll.

**7.1.1 Will I need to pay anything to be part of the study?** To be part of the study, you will need to pay for [indicate what costs, if any, participants will have to pay (such as parking)]. Delete this section if there are no costs to participants.

### **7.2 Who could profit or financially benefit from the study results?**

The sub-headings under this question related to potential conflict of interest scenarios. Delete this section 7.2 if none of these scenarios apply to this study. If a person or organization involved in the conduct of this study has or may have a conflict of interest, address any of the following issues that may apply:

- How is the research supported or financed?
- Where and by whom was the study designed (i.e., industry-sponsored versus investigator-initiated)?
- Do individuals or the institution receive any compensation that is affected by the study outcome?
- Do individuals or the institution
  - (1) have any proprietary interests in the product (including patents and licensing agreements);
  - (2) have an equity interest in the sponsor;



- (3) receive significant payments of other sorts (e.g., grants or consultant retainers); and/or
- (4) receive payment per participant or incentive payments?

The company whose product is being studied:

Disclose under this sub-heading if a company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study, particularly if the company/organization is also the sponsor of the study or has a financial relationship with the investigators (as described under the next sub-heading). Delete this sub-heading if it does not apply.

The researchers conducting the study:

**Information regarding suggested language for this section:**

If any of the investigators on the study have an ownership, consulting, or similar financial relationship with the sponsor, they should disclose it here in accordance with the management plan approved by the Conflict of Interest Committee. If your plan is reviewed and approved by the Institutional Conflict of Interest Committee (ICOC), your plan may include suggested/required language. Please review your plan accordingly. Delete this sub-heading if it does not apply.

**Suggested Language if there is a Tech Transfer/Financial Interest:**

The Phronetik Office for Research is an owner and [CONFLICTED INDIVIDUAL'S NAME HERE] is a named inventor on patents or patent applications or is a creator of copyrighted material that is licensed or optioned to [STATE COMPANY NAME]. This means, Phronetik and [CONFLICTED INDIVIDUAL'S NAME HERE] could gain financially from this study. Delete this sub-heading if it does not apply.

**Suggested Language if there is Stock Ownership:**

[STATE CONFLICTED INDIVIDUAL'S NAME HERE] owns stock or stock options in [COMPANY NAME] who is the [SPONSOR/MANUFACTURER] of the [PRODUCT] being studied. Delete this sub-heading if it does not apply.

**Suggested Language if there are Other Financial Interests (Paid):**

[STATE CONFLICTED INDIVIDUAL'S NAME] serves as a paid [STATE POSITION] for [COMPANY NAME] on topics [RELATED/UNRELATED] to this study. [COMPANY NAME] is the [SPONSOR/MANUFACTURER] of the [PRODUCT] being studied. Delete this sub-heading if it does not apply.

**Suggested Language if there is Other Non-financial Interests (Unpaid):**

[STATE CONFLICTED INDIVIDUAL'S NAME] serves as an unpaid [STATE POSITION] for [COMPANY NAME] on topics [RELATED/UNRELATED] to this study. [COMPANY NAME] is the [SPONSOR/MANUFACTURER] of the [PRODUCT] being studied. Delete this sub-heading if it does not apply.

**Suggested Language if there is a Relative/Family-Related Conflict of Interest:**



[STATE CONFLICTED INDIVIDUAL'S NAME, STATE RELATIONSHIP TO YOU.]  
Delete this sub-heading if it does not apply.

**Suggested Language if the Phronetik Office for Research has a financial interest in the future:**

If Phronetik intends to be paid licensing fees for the investigational technology, **or could in the future**, so disclose under this sub-heading (e.g., when there is a tech transfer agreement in place or anticipated for which the Phronetik Office for Research and/or creators could be paid licensing fees). Contact Office of Sponsored Research (OSR) if you are uncertain. Delete this sub-heading if you are certain it does not apply.

## 8. PROTECTING AND SHARING RESEARCH INFORMATION

**8.1 How will the researchers protect my information?** Describe procedures that will be followed to keep participant information secure and confidential. Note: any research data that will be linked to individual identifiers is considered identifiable.

**8.1.1 Special Protections (Delete this section if not applicable)**

If your project is **NIH-funded and collects identifiable, sensitive information**, it will be covered by an NIH Certificate of Confidentiality, or if **you will apply for a CoC** for non-NIH sponsored research collecting health-related, identifiable, sensitive information, use the following required language:

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, **[Cite examples as apply to your research]** we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- **[Insert this statement only if applicable]** The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.



More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc/what-is.htm>

## 8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- Phronetik Office for Research, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- **If applicable, state:** If you receive any payments of \$100 or for taking part in this study, the Phronetik accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- **If applicable, state:** Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

## 8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the research [for future research projects/for study recordkeeping or other purposes (describe)]. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. **Note: any research data that will be linked to individual identifiers is considered identifiable. Linking of data to individual identifiers, length of time data will be linked to identifiers, and whether destruction of identifiers will occur should be described here.**

**For longitudinal research:** The researchers [plan to/may] contact you again as part of this project.

**Or:** We will not keep your name or other information that can identify you directly.

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

**If the investigator wishes to identify a participant in a presentation or article, state:** The results of this study could be published in an article or presentation, but would not include any information that would let others know who you are without your permission.

## 8.4 Will my information be used for future research or shared with others?

The Common Rule requires that investigators tell participants whether their data will be stored and shared for future research, even if de-identified.

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will



not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

If you plan to retain and share identifiable information for unspecified future research, state: We would like to share your identifiable information with other researchers for future research. We will ask for your consent to do so at the end of this form. You can be a part of this current research project without agreeing to this future use of your identifiable information.

or We will not store your research information or share it with other researchers. The IRB does not recommend the use of this statement, as it will preclude the secondary use of these data in the future.

#### **8.4.1 Special Requirements (Delete this section if not applicable.)**

**If your project is NIH-funded and meets the definition of an NIH clinical trial, include the following required language:** A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**If you will register your project on ClinicalTrials.gov voluntarily or in order to meet journal or other requirements, include the following:** This trial will be registered and may report results on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). This site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**For projects that will contribute research data to a repository, use the following language:** We will put the information we collect from you into a repository. The repository contains information about many people. Your information will be [de-identified –or- labeled with a code, instead of your name or other information that could be used to directly identify you.] Add additional information regarding data protections provided by the repository.

## **9. CONTACT INFORMATION**

### **Who can I contact about this study?**

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

### **Principal Investigator:**





PHRONETIK

Office for Research

**Email:**  
**Phone:**

**Email:**  
**Phone:**

**Study Coordinator (if applicable; delete if does not apply):**

**Email:**  
**Phone:**

**For international studies**, include the US Country Code for the phone numbers above. Include the name, email, and phone number for the local collaborator, if any.

**If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:**

Phronetik Inc.

Office of Sponsored Research

1011 Surrey Lane, BLDG 200

Flower Mound, TX 75022

844.871.3575 | [osr@phronetik.com](mailto:osr@phronetik.com)

**For international studies**, include the US Country Code for the IRB-OHSR phone number. For projects reviewed by an in-country IRB or ethics committee, include contact information for that organization and place it before the IRB-OHSR contact information.

You can also contact the Phronetik Compliance Hotline at 1-844-871-3575

## 10. YOUR CONSENT

### **Consent/Assent to Participate in the Research Study**

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

Print Legal Name: \_\_\_\_\_



Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

Investigators are reminded that they should give a copy to the participant and retain a full copy of the consent including a copy of the signature page as part of your research records. Participants must complete all of the required information (printed name, signature and date).

**Parent or Legally Authorized Representative Permission (delete this section if it does not apply)**

By signing this document, you are agreeing to [your child's] **or** [the person's named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child] **or** [the person named below] to take part in this study.*

\_\_\_\_\_  
Print Participant Name

\_\_\_\_\_  
Print Parent/Legally Authorized Representative Name  
Relationship to participant:  Parent  Spouse  Child  Sibling  Legal guardian  Other

\_\_\_\_\_  
Signature Date

\_\_\_\_\_  
Printed Parent/Legally Authorized Representative Name (when two parent signatures are required) Two signatures are required for more than minimal risk research with no direct benefit to the child.  
Relationship to participant:  Parent  Sibling  Legal guardian  Other

\_\_\_\_\_  
Signature Date

*Reason second parent permission was not collected:*  
 Parent is unknown



- Parent is deceased
- Parent is incompetent
- Only one parent has legal responsibility for care and custody
- Parent is not reasonably available\*; explain:

*\* Note: "Not reasonably available" means the other parent cannot to be contacted by phone, mail, email, or fax, or his or her whereabouts are unknown. It does not mean that the other parent is at work or home, or that he or she lives in another city, state, or country.*

## 11. OPTIONAL CONSENT

Separate signatures should be obtained for specific activities when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the consent document. Some common optional research activities are included below. Delete this section or any of the following consent statements that do not apply to your research. Participants must complete all of the required information (printed name, signature and date) if an optional consent section is offered.

**Consent to use [video recordings/audio recordings/photography] for purposes of this research. (Use this ONLY if recording is not required to participate in the research.)**

This study involves [video recordings/audio recordings/photography]. If you do not agree to be [video recorded/audio recorded/photographed], you can still take part in the study.

\_\_\_\_\_ Yes, I agree to be [video recorded/audio recorded/photographed].

\_\_\_\_\_ No, I do not agree to be [video recorded/audio recorded/photographed].

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

**Consent to use of video recordings, audio recordings or photographs for publications, presentations or for educational purposes.**

I give permission for audio recordings/video recordings/photographs made of me as part the research to be used in publications, presentations or for educational purposes.

\_\_\_\_\_ Yes

\_\_\_\_\_ No



Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

**Consent to use and/or share your identifiable information for future research**

The researchers would like to use your identifiable information for future research that may be similar to or completely different from this research project. Identifiable means that the data will contain information that can be used to directly identify you. The study team will not contact you for additional consent to this future research. We may also share your identifiable information with other researchers. You can contact us at any time to ask us to stop using your information. However, we will not be able to take back your information from research projects that have already used it.

Note: This separate consent is not necessary if you will only store and share de-identified data or biospecimens.

\_\_\_\_\_ Yes, I agree to let the researcher(s) use or share my personally identifiable information for future research.

\_\_\_\_\_ No, I do not agree to let the researcher(s) use or share my personally identifiable information for future research.

Print Legal Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date of Signature (mm/dd/yy): \_\_\_\_\_

**Consent to be Contacted for Participation in Future Research**

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

\_\_\_\_\_ Yes, I agree for the researchers to contact me for future research projects.

\_\_\_\_\_ No, I do not agree for the researchers to contact me for future research projects.



**Include this HIPAA Authorization form if your research project requires access to or disclosure of identifiable Protected Health Information from a HIPAA covered entity as part of the research**

## HIPAA Authorization

### Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at [name of covered entity or entities] to use or disclose (release) your health information that identifies you for this research study.

The health information to be used for this research includes: [Provide a description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.]

The health information listed above may be used by and/or disclosed (released) to: [Name or class of persons involved in the research; i.e., researchers and their staff]

[Name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that [name of covered entity (ies)] has already acted based on this Authorization. To revoke this Authorization, you must write to [name of the covered entity(ies) and contact information].

This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as "end of the research study."]

\_\_\_\_\_  
Signature of participant or participant's  
personal representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of participant or  
participant's personal representative

\_\_\_\_\_  
If applicable, a description of the personal

representative's authority to sign for the  
participant