Baylor University

**Department of Computer Science**

Consent Form for Research

PROTOCOL TITLE: **Using the Leap Motion to Extend Mid-Air Word- Gesture Keyboards**

PRINCIPAL INVESTIGATOR: Garrett Benoit

SUPPORTED BY: **Baylor University**

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| **INSTRUCTIONS:**  This template is only part of the informed consent process. Many sections of this document include brief instructions and wording suggestions **in bold font** to provide investigators with a general overview of information required in the section. The instructions/information in **bold font** should be replaced with your protocol-specific information.  Please note that not all of the information in this form will apply to your study. Please delete any sections that do not apply to your study and add any information that applies to your study but is not included in this template. This is only a template and should be used as a guide. The Principal Investigator is responsible for ensuring that the study details are included in the consent form.  **Please delete all shaded instruction boxes prior to submitting this form to the IRB.** |

**Introduction**

Please read this form carefully. The purpose of this form is to provide you with important information about taking part in a research study. If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Taking part in this research study is up to you. If you decide to take part in this research study we will ask you to sign this form. We will give you a copy of the signed form.

The person in charge of this study is Garrett Benoit, under the guidance of Dr. G. Michael Poor**.** We will refer to this person as the “researcher” throughout this form.

**Why is this study being done?**

The purpose of this study is to **[Briefly explain the purpose of the study]**

We are asking you to take part in this study because you **are/have [Specify reason for recruitment.]**

About 14 subjects will take part in this research study at Baylor University.

**How long will I take part in this research study?**

We expect that you will be in this research study for no longer than 60 minutes. During this time, we will ask you to make one study visit to the Human Computer Interaction lab in room **<verify room number>** of the Rogers Engineering & Computer Science building located across from the Wiethorn Visitor's Center.

**What will happen if I take part in this research study?**

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| **INSTRUCTIONS:** Provide a list of all study procedures/tests/activities and when they will occur. Include the following information:   * The length and duration of visits and procedures. * Which procedures are being performed as standard of care and which are part of the research study, when applicable. Do not include procedures that would occur regardless of the subject’s participation unless it would aid the subject’s understanding of the study. * Information about the study design, e.g., randomization * Special requirements, e.g., stopping current medications, fasting before tests * Reasons and procedures for early withdrawal from the study * Sending data/specimens to research collaborators * Storage of data/specimens for future use   Study-related procedures should be chronological (such as by visit). You can also list all study procedures and then include a chart indicating at which visit(s) the procedure will occur. |

If you agree to take part in this study, we will ask you to sign the consent form before we do any study procedures.

**Study Visit 1**

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| **INSTRUCTIONS:** Below is a list of common possible procedures. Customize this list for your study. Use the format below for all subsequent study visits (Visit 2, Visit 3, etc.) |

Visit 1 will take about 60 minutes to complete. At this visit, we will ask you to do the following procedures:

* Give you some questionnaires to fill out about **your physical health, mood, mental and emotional health, quality of life, and habits**
* Ask about your medical and mental history
* Ask about your medications
* Measure your vital signs (blood pressure, temperature, heart and breathing rates)
* Give you an ECG (electrocardiogram). This test checks the electrical activity of your heart. We will place several, small, sticky pads on your chest, arms, and legs. There is a wire attached to each pad. The wires connect to a machine that makes a recording of your heart rhythm.
* Interview you about your experiences with **describe subject.**
* Take part in a focus group. A focus group is a small group of people who take part in a discussion about a selected topic. The focus group will be led by a member of the research staff. The focus group leader will ask the group members about their opinion of **topic.**
* Give you an MRI (magnetic resonance imaging) of your **body location**. A MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. During the MRI, we will ask you to lie still on a table that slides into a tunnel-shaped machine. The machine is slightly wider than your body. The top and sides of the tunnel will be very close to your body. The MRI machine makes loud noises as it take pictures of the insides of your body. We will give you earplugs to reduce the noise. You will be able to hear and speak to the research staff at all times during the MRI procedures. We can stop the procedure at any time, if necessary. The MRI will take about **amount of time.**
* Ask you to complete tasks on the computer
* Give you an EEG (electroencephalogram). An EEG is a test that measures and records the electrical activity of your brain. We will put special sensors (electrodes) on your head. There is a wire attached to each sensor. The wires connect to a computer. The computer records your brain's electrical activity on the screen or on paper as wavy lines.
* Give you a DXA (or DEXA) scan. A DXA is a type of x-ray used to measure bone strength. During this test, X-ray pictures of your body will measure how much fat and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of the body. This test will last about **amount of time**.

**What are the risks of taking part in this research study?**

To the best of our knowledge, taking part in this study will not hurt you.

**Risks of Completing Tasks**

You may get tired during the tasks. You can rest at any time.

**Questionnaire/Survey Risks**

You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.

**Loss of Confidentiality**

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The researcher plans to protect your confidentiality. Their plans for keeping your information private are described later in this consent form.

**Are there any benefits from being in this research study?**

There are no benefits to you from taking part in this research.

Others may benefit in the future from the information that is learned in this study.

**What alternatives are available?**

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| **INSTRUCTIONS:** List any alternatives. If there is no alternative to participation, the statement below is sufficient. |

You may choose not to take part in this research study.

You do not have to take part in this research study to receive course credit. Your alternative for equal credit is **state alternative**

**Storing Study Information for Future Use**

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| **INSTRUCTIONS:** If you would like to store data for future research, include the information below. Chose the correct language concerning whether it is optional or not. |

We would like to store your study information for future research related to **condition/topic (e.g., depression, memory, learning, etc.)**. We will label all your study information with a code instead of your name. The key to the code connects your name to your study information. The researcher will keep the code in a **password-protected computer/locked file.**

Future use of study informationis **required/optional** for this study**. (If required)** If you do not want your information to be used for future research, you should not be in this study. **(If optional)** If you do not want your information to be used for future research, you can still be in the study. You will indicate your decision at the end of this form.

**How Will You Keep My Study Records Confidential?**

We will keep the records of this study confidential by **[state how you will ensure that the subject’s records are kept confidential].** We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

**Reporting child/elder abuse, if applicable:** If, during your participation in this study, we have reasonable cause to believe that **child/elder** abuse is occurring, this will be reported to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court will demand the release of identifiable research information.

**Reporting risk of harm to self or others:** If, during your participation in this study, we have reason to believe that you are at risk for harming yourself or others, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

The following people or groups may review your study records for purposes such as quality control or safety:

* The Researcher and any member of **his/her** research team
* Authorized members of Baylor University who may need to see your information, such as administrative staff members from the Office of the Vice Provost for Research and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)
* The sponsor or funding agency for this study
* Federal and state agencies that oversee or review research (such as the HHS Office of Human Research Protection or the Food and Drug Administration)

The study data will be stored **state where data will be stored.**

The results of this study may also be used for teaching, publications, or presentations at professional meetings. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

**If Certificate of Confidentiality is Obtained:** We have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS) for this study. This certificate adds special protection for research information that identifies you. This Certificate does not mean that the government approves or disapproves of this study.

With this Certificate, we cannot be forced (for example by court order or subpoena) to release any identifying research information about you. You should understand that the Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research study. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate does not prevent the researchers from voluntarily disclosing, without your consent, information that would identify you as a subject in this research study if we: 1) are concerned that you may be suicidal (thinking about killing yourself) or at immediate risk of seriously harming yourself or others, or 2) learn about serious harm to you or someone else (such as child abuse or elder abuse). Under these circumstances we will notify the appropriate people (such as your personal doctor, counselor, local or state agency, or other authorities).

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| **INSTRUCTIONS:** Include the following paragraph if the study will be registered on clinicaltrials.gov to meet FDAAA clinical trials registration requirements. This requirement applies to certain clinical trials of drugs (including biological products) and medical devices. This paragraph must be included even if the sponsor is the responsible party for clinical trials registration. This paragraph is not required when registering only to meet journal requirements. For guidance, go to www.clinicaltrials.gov.  The below paragraph **cannot** be edited. |

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 any information that can identify you. At most, the Web site will include a summary of the results of this research. You can search this Web site at any time.

**Study Participation and Early Withdrawal**

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. You cannot withdraw information collected prior to your withdrawal.

**If you are a student at Baylor University:** You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or your grades at Baylor University. You will not be offered or receive any special consideration if you take part in this research study.

The researcher may take you out of this study without your permission. This may happen because:

* The researcher thinks it is in your best interest
* You can’t make the required study visits
* Other administrative reasons

**Will I get paid for taking part in this research study?**

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| **INSTRUCTIONS:** Include the following information in this section:   * Provide specific information about payment (money or other forms of compensation or reimbursement, e.g., gift certificate, meal voucher, parking voucher, and travel expenses) * Include how the amount of compensation is calculated if the subject does not complete the entire study for any reason, e.g., “If you do not complete all of the study visits, we will give you $25 for each study visit you completed.” * State when subjects will be paid (e.g. after each visit or after study is completed, etc.) * For lottery/raffle drawings, include the following: when the drawing will occur, who will conduct the drawing, how payment will be made, the value of the prize, the number of prizes, and the chances of winning.   **Note: If participants will not be paid or will not receive other forms of compensation for participation, please state.**  **See sample statements below.** |

Mention food voucher for people who aren't recruited with the guise of extra credit.

We will give you **state amount of course credit** for taking part in this study.

**What will it cost me to take part in this research study?**

There are no costs to you for taking part in this research study.

**What if I have any questions or concerns about this research study?**

You can call us with any concerns or questions about the research. Our telephone numbers are listed below: **List contact information for PI and/or other applicable study staff. State the hours that study staff can be contacted. If you are a student, include the contact information for your Faculty Advisor.**

If you want to speak with someone **not** directly involved in this research study, you may contact the Baylor University IRB through the Office of the Vice Provost for Research at 254-710-1438. You can talk to them about:

* Your rights as a research subject
* Your concerns about the research
* A complaint about the research

**Indicate your decision for the below optional research discussed earlier in this form:**

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| **INSTRUCTIONS:** If there are any optional decisions for the subject to make, add appropriate language and choices. Common decisions are listed below. |

**Optional Consent for future research with study information:**

Do you agree to let us store your study information for future research related to **condition/topic**?

\_\_\_\_\_\_YES \_\_\_\_\_\_NO \_\_\_\_\_\_\_INITIALS

**Future Contact**

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| **INSTRUCTIONS:** If you want to contact the subject in the future for follow-up questions or to recruit for future studies, add the language below. |

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Baylor University.

Do you agree to let us contact you in the future?

\_\_\_\_\_\_YES \_\_\_\_\_\_NO \_\_\_\_\_\_\_INITIALS

**Statement of Consent**

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| **INSTRUCTIONS:** Include signature line(s) as appropriate to the subject population and consent process described in the protocol documents. Delete those signature lines that are not applicable. If you are requesting a waiver of documentation of consent, delete all signature lines. If consent is being obtained via the internet, insert language such as “By clicking “I Agree” you are providing consent to be in the study.” |

**SIGNATURE OF SUBJECT:**

I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

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Signature of Subject Date

**Signature of Person Obtaining Consent:**

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

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Signature of Person Obtaining Consent Date