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| **STUDY TITLE** | Alternatives using the Leap Motion for Mid-Air, Word-Gesture Keyboards |
| **PI NAME** | Garrett Benoit |

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| **Proposed Change(s) (check all that apply)** | | |
| 1. |  | Change in the Principal Investigator |
|  | Change in research staff (other than PI) |
|  | Change in the number of participants |
|  | All other research changes |

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| **Revised Document(s) (check all that apply)** | | |
| **2.** | Check the document(s) that require revision or are new. | |
|  | Change in the Principal Investigator |
|  | Change in research staff (other than PI) |
|  | Consent Form(s), Assent Form(s), Permission Form(s), Information Sheet(s), Consenting Script(s) |
|  | Recruitment Materials (e.g., ads, flyers, scripts, internet solicitations) |
|  | Study tools (e.g., questionnaires, surveys, instructions) |
|  | Other. Specify:The Protocol itself and the application. (sample size, condition, and date change) |
| **For all items checked, provide the revised materials as:**   * **One copy with the change(s) underlined (“tracked”) and** * **One copy with the change(s) incorporated (“clean”).** | |

**For each proposed change checked in #1, fill out the appropriate section below.**

**Change in Principal Investigator**

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| **3.** | **Provide the proposed PI’s contact information** | |
| Name: | Degree(s): |
| Title: | Phone: |
| BU Home Department: | |
| Address: | Email: |

**BU Position or Appointment (choose the most appropriate one):**

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| **4.** | **a.** |  | Tenured/Tenure-track Faculty | |  | Visiting Faculty | |
|  | Research Faculty | |  | Adjunct Faculty | |
|  | Clinical Faculty | |  | Lecturer Faculty | |
|  | Joint Appointment. Home Institution: | |  | Postdoctoral | |
|  |  | |  | Other: | |
| **If student:** | | |  |  | |
|  | Undergraduate student | Faculty Advisor:  Department Chair: | | | |
|  | Graduate or Professional Student  (degree program): |
|  | | | | | |
| **b.** | Has the PI ever been debarred, restricted, or disqualified by any federal agency (FDA, ORI, PHS, etc.)? | | | | | Yes  No |
| **c.** | Does the PI have any current proceedings for debarment, restriction, or disqualification? | | | | | Yes  No |
| **d.** | Is the PI excluded from receiving federal contracts, certain subcontracts, and from certain types of federal financial and nonfinancial assistance and benefits [i.e., listed on the Excluded Parties List System (EPLS)]? | | | | | Yes  No |
| **e.** | Has the PI been audited or investigated by the Office of Human Research Protections (OHRP) or the Food & Drug Administration (FDA) within the last 5 years? | | | | | Yes  No |

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| **5.** | Provide rationale for change in PI: |

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| **6.** | Explain the proposed PI’s qualifications to assume responsibility for the research: |

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| **7.** | Has the sponsor or funding source of the study been notified of the change in PI?  **If no,** explain: | Yes  No |

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| **8.** | Will the former PI continue to have a role in the research?  **If yes,** explain: | Yes  No |

**Change in research staff**

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| **9.** | **a.** | List all additions and/or removals. | | | |
| Name | Add | | Remove |
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| If additional space needed, attach a separate page. | | | |
| **b.** | Do all new research staff have current CITI training?  \*\*\*Approval of this change may be delayed due to expired training or new staff that have not completed the required training. **NOTE**: As the Principal Investigator, you are responsible for ensuring that all research staff have completed any other University of facility required training, such as training required by EHS. | | Yes  No  N/A | |
| **c.** | Do any new research staff have a conflict of interest not previously reported?  **If yes,** identify the individual, the conflict, and how it will be managed: | | Yes  No  N/A | |

**Change to the number of participants**

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| **10.** | **a.** | Enter currently approved number: 14 |
| **b.** | Enter proposed number: 18 |
| **c.** | Provide rationale for the change in numbers: One of the conditions is being removed bringing it down from 7 keyboard inputs to 6 keyboard inputs. In order to preserve the Replicated Latin Squares design, the sample size needs to be changed to either 12 or 18. A larger sample size of 18 provides more statistical power. |

**All other changes**

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| **11.** | **a.** | Describe the change(s) to the research and provide a rationale for each change.  One of the conditions is outside of the scope of this study and is being removed and relocated to the future works section of the thesis. This change requires a change in sample size, from 14 to 18, to preserve the Replicated Latin Squares design. The extra time gained during the study visit from the removal of the condition will be spent on increasing the trials per condition from 10 to 15. The discarded condition was removed from the exit survey/intermittent keyboard survey. Lastly, due to these changes, the anticipated completion of the study is being extended by one month to October 1st. | |
| **b.** | Will there be any change in the risk(s) to participants?  **If yes,** explain: | Yes  No |
| **c.** | Will there be any change in the benefit(s) to participants? NOTE: Compensation is not to be considered a benefit.  **If yes,** explain: | Yes  No |
| **d.** | Could the proposed change(s) affect participants’ willingness to take part in the research?  **If yes,** how will information be communicated to currently enrolled subjects (e.g., revised consent form, letter to participants, etc.)? | Yes  No |