**WILLIAM MARSH RICE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD (IRB)**

**FOR THE PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS**

**APPLICATION FOR NEW PROTOCOL REVIEW**

For applications requiring full board review, please access the following website

for information regarding scheduled board meetings: <http://osr.rice.edu/irb-dates.cfm>

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For applications not requiring full board review (exempt or expedited), allow two (2) weeks for

protocol review following receipt of all required documents.

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| **FOR IRB USE ONLY  PROTOCOL NO:**  **APPROVAL DATE:** |
| **MODIFICATION NUMBER** **MODIFICATION APPROVAL DATE**: |
| **OSR NO:** |

## E-MAIL ALL FORMS TO [jpeno@rice.edu](mailto:jpeno@rice.edu). All protocols must be submitted by Principal Investigator.

Address questions to Compliance Administrator - Jamie Peno ([jpeno@rice.edu;](mailto:jpeno@rice.edu) 713-348-3586).

The Principal Investigator and all researchers on the proposed project must complete the [CITI](https://www.citiprogram.org) online IRB training course

**prior to initiation of the project.** Note that a passing grade of 80% is required for **each** module.



1. Activity Title (Title should be the same as a grant/proposal title, if funded by an external sponsor.)

**Massive Manipulation: An online user study on controlling large swarms of simple robots**

2. Principal Investigator(s) (the Principal Investigator must be a Rice faculty member or equivalent)Complete **all** blocks for each Principal and Co-Investigator listed.

Principal Investigator

|  |  |
| --- | --- |
| Name: | **James McLurkin** |
| Department: | **Computer Science** |
| Telephone: | **713-348-3049** |
| Mail Stop: | **132** |
| E-mail: | **jmclurking@rice.edu** |

Co-Investigator(s)

|  |  |
| --- | --- |
| Name: | **Aaron Becker** |
| Department: | **Computer Science** |
| Telephone: | **217-722-2058** |
| Mail Stop: | **132** |
| E-mail: | **ab55@rice.edu** |

Co-Investigator(s)

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Co-Investigator(s)

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**Note: This application MUST be submitted by the Principal Investigator, who assumes full responsibility**

**for compliance with this protocol.**

**PRELIMINARY INFORMATION** **REQUIRED FOR IRB REVIEW DETERMINATION**

**SECTION 1:** Is this a research activity using human subjects and thus requiring IRB review and approval? (see below)

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| Is the activity a systematic investigation of multiple human subjects, including research testing and evaluation?  Yes  No |
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| Is the activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge?   Yes  No |
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| Are all specimens/data collected from subjects who are known to be deceased?   Yes  No |

**SECTION 2:** Exemption Categories [45 CFR 46.101(b)]

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| **Exemption (b)(1)** - Will the research be conducted in established or commonly accepted educational settings,  involving normal education practices such as (i) research on regular and special education instructional strategies, or  (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods? (This may include schools, colleges, and other sites where educational activities regularly  occur)  Yes  No |
|  |
| **Exemption (b)(2)** - Will the research involve the use of educational tests, survey procedures, or observation of public behavior?  Yes  No \*NOTE - research involving children is not eligible for this exemption.  *If ‘Yes’,* *check all that apply*:  Educational tests  Surveys  Interviews  Observation of public behavior |
|  |
| **Exemption (b)(3)** - Will the research involve the use of educational tests, survey procedures, or observation of public behavior wherein the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter?  Yes  No |
|  |
| **Exemption (b)(4)** - Does the research only involve the use or study of existing (already available or on the shelf) data, documents, records, or pathological or diagnostic specimens?  Yes  No If ‘yes’, check any items below that  will be collected or studied. *(check all that apply)*   Existing data  Existing documents  Existing records  Existing pathological specimens   Existing diagnostic specimens  Is this information publically available?  Yes  No  What is the source of the information or material? Include hyperlink, if known.  Provide the name and hyperlink for blood/tissue bank.  Will information be recorded in a manner that research participants cannot be identified, directly or through identifiers linked to the participants?  Yes  No |
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| **Exemption (b)(5)** - Does the research evaluate or examine public benefit or service programs, such as demonstration or dissemination projects?  Yes  No |
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| **Exemption (b)(6)** - Does the research involve taste and food quality evaluations?  Yes  No  If yes, what is the purpose of this study *(check all that apply)*?   To evaluate the taste or quality of food  To test consumer acceptance of a food |

**SECTION 3:** Additional Information:

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| 1. Expected Age Range of Participants: *(check all that apply*  18 and above  minors under the age of 18  2. Will this study include embryonic stem cells?  Yes  No  3. Does this study include a diagnostic procedure that is medically indicated?  Yes  No  4. Does this study include disinfectant/sterilization procedure(s) used for study instrumentation?  Yes  No  If yes, please summarize procedures.  5. List any contrast agents to be applied to study subjects:  6. If this is a collaborative study, are any additional clinical procedures added to accommodate the Rice portion of the study?  Yes  No If yes, please explain:  7. List any instrumentation to be used that was built by Rice personnel:  8. Are you or will you be seeking [FDA approval](http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/default.htm) for a  [device](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm),  [drug](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2a88f275a8609a20ed3f25adbeb7205f&rgn=div5&view=text&node=21:5.0.1.1.3&idno=21), or  [therapeutic](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/default.htm)?  9. Is this protocol being conducted under an [Investigational Device Exemption](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051616.htm) (IDE)?  Yes  No |

**DETAILED INFORMATION** **REQUIRED FOR IRB REVIEW AND APPROVAL:**

**Please answer ALL questions below or indicate exemption under (b)(4). If a question does not apply to your study, please enter “N/A” in the appropriate box.**

4. Study funding: Will this study be funded by an external sponsor?  Yes  No  
 If yes, please complete the information below.

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| --- |
| Sponsoring agency(s): **NSF** |
| Grant Number (if already funded): **----** |
| Rice Fund Number (if already funded): |

|  |
| --- |
| If Rice is a subcontractor to another entity, list the prime source of funding (e.g., NSF) if known. |

5. Proposed Start Date (actual date may not precede IRB approval date) **July 2013**

6. Describe the purpose of the research. **Compare and contrast several control techniques for directing swarms of (simulated) robots**

7. Participant Recruitment: describe the source(s) of potential participants; how they will be selected and

recruited; and how and how you will contact them. Describe all relevant characteristics of the participants with regard to age, ethnic background, gender, institutional status (i.e., patients or prisoners), and their general state of mental and physical health. **We will recruit colleagues, students and general internet users to complete a game-like simulation on the internet (http://swarmcontrol.herokuapp.com/).**

**\*or check here**  **if this project qualifies for exemption under (b)(4).**

8. Describe procedures to be used and any associated risks or discomforts. **Procedures should be specific and listed step by step. The simulation times the users as they attempt various tasks. paarticipation is voluntary, and users may exit the simulation website at any time. or check here  if this project qualifies for exemption under (b)(4).**

9. Describe **in detail** any safeguards to minimize risks or discomforts, including any measures to render the data anonymous **i.e., you will not know the identity of the research subject** or confidential **i.e., subjects’ identity or personal identifying information will not be disclosed**. Please be reminded that anonymity and confidentiality are not synonymous terms. **We will use an IP anonymizer. We will not know the identity of the research subject**

**\*or check here  if this project qualifies for exemption under (b)(4).**

10. Describe any financial compensation or other potential benefits to the subjects associated with this research activity. If none, please indicate this in the box as “N/A”. **N/A**

\***or check here  if this project qualifies for exemption under (b)(4).**

11. Does the proposed human subject research involve a financial or other interest of the PI or Co-PI?

Yes  No (see <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>) If yes, please explain below.

12. Is the consent form attached?  Yes  No  Waiver requested [please justify the need to waive this requirement or attach a separate document to the application.]

**\*or check here  if this project qualifies for exemption under (b)(4).**

13. The IRB must review all materials to be seen or heard by the study participants. Are **all** materials (i.e., survey, interview questions, videos, etc.) referenced in the application form attached?  Yes  No  
 If no, please explain.

**\*or check here  if this project qualifies for exemption under (b)(4).**

14. Benefits and Risks: Please explain how the potential benefits to the subjects and/or the anticipated gain in research knowledge outweigh the risks to the subjects. (Be specific and succinct - do not simply “justify” the research.)

**\*or check here  if this project qualifies for exemption under (b)(4).**

15. List all institution(s) involved in the proposed research (other than the funding source) that are recruiting participants, analyzing data, etc. Attach copies of their IRB approvals (including consent forms), as applicable. If copies are not attached, please explain. **N/A**

16. After reviewing Part 46 of the Code of Federal Regulations (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>), please check the appropriate box stating your judgment as to the required level of review for this study.

Exempt from further IRB review  Expedited  Full Board review required

**THIS SPACE FOR IRB USE**

PROTOCOL NUMBER:

ACTIVITY TITLE:

**APPROVAL DECISION:**

The protocol has been determined to be exempt from IRB review in accordance with

Title 45, Part 46, Section 46.101  of the Code of Federal Regulations.

Exempted by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_on behalf of the IRB.

Jamie Peno, Compliance Administrator

Exemption approval date:

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The protocol has been approved through expedited review in accordance with Title 45, Part 46,

Section 46.110 of the Code of Federal Regulations. **(Category**  **)**

Without contingency(s) With contingency(s)  Contingency(s) met

The IRB has approved the protocol through full review in accordance with Title 45, Part 46,

Section 46.111 of the Code of Federal Regulations.

Without contingency(s) With contingency(s)  Contingency(s) met

IRB Approving Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
 Dr. John Cornwell – IRB Chair

Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_