**REQUEST FOR IRB REVIEW OF EXEMPT RESEARCH INVOLVING HUMAN SUBJECTS**

**FOR PROTOCOLS INVOLVING TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR**

**45 CFR 46.101(b)(2)**

Please complete this application as thoroughly as possible. Your application should include the following:

1. A copy of any questionnaires, interviews, surveys, scripts, etc. that will be used.
2. A copy of any recruitment documents (including advertisements, flyers, letters, invitations, email) to be used;
3. A copy of the training certificates for all individuals working on the research unless it is on file with the CMU IRB. Training is available at: <http://phrp.nihtraining.com/users/login.php>
4. If the PI is a student, the faculty advisor must submit a Faculty Advisor Assurance Form.

Please email all documents to irb-review@andrew.cmu.edu. For assistance call CMU Research Compliance @ 412-268-5460 or email irb-review@andrew.cmu.edu. Additional information and templates are available at <http://www.cmu.edu/osp/regulatory-compliance/human-subjects.html>

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| **1. Protocol** |
| Title:  Children's knowledge of architecture |
| [ ]  This is a previously approved study that has lapsed.  | Previous IRB No: HS      |
| **2. Principal Investigator (PI)** |
| Name: Kelly Lyons | Department: Architecture |
| Telephone: 412-268-1541 | E-mail: kellyons@cmu.edu | Training Cert. [ ]  Attached [ ]  On File |
| [x]  I am a student. If so, please provide information about your faculty advisor below. |
| Faculty Advisor Name: Brian Junker | E-mail:bj20@andrew.cmu.edu | Training Cert. [ ]  Attached [ ]  On File |
| *If a student is the PI, the faculty advisor must complete and submit a Faculty Advisor Assurance Form.* |
| If there is someone other than PI to correspond with regarding this protocol, please list below. |
| Contact Person Name:      | Telephone:       | E-mail:       |
| Business Manager for your department:David Koltas | E-mail: dkoltas@andrew.cmu.edu |
| **3. Co-investigators** |
| Name: Erica Cochran | E-mail: ericac@andrew.cmu.edu | Training Cert. [ ]  Attached [ ]  On File |
| Name:       | E-mail:       | Training Cert. [ ]  Attached [ ]  On File |
| Name:       | E-mail:       | Training Cert. [ ]  Attached [ ]  On File |
| Name:       | E-mail:       | Training Cert. [ ]  Attached [ ]  On File |
| Name:       | E-mail:       | Training Cert. [ ]  Attached [ ]  On File |
| **4. Funding** |
| [x]  Unfunded research | Sponsor/Source:       |
| [ ] External Funding | SPEX Proposal #:       |
| [ ]  Internal Funding  | Oracle String:      |
| Grant Title:       |
| *If you don’t know the funding/grant information, please get it from your department’s business manager.* |
| **5. Eligibility for Exempt Determination per 45 CFR 46.101(b)(2)** |
| 1. What type(s) of instruments/activities will be used *(check all that apply)*? [x]  Educational tests (cognitive, diagnostic, aptitude, achievement) [ ]  Surveys [ ]  Interviews [ ]  Observation of public behavior

*If the research involves other activities, it is not eligible for this exemption. Do not proceed.* *Use the standard CMU IRB Application.* |
| 1. Will information be recorded in a manner that participants can be identified [ ]  Yes [x]  No
 |
| 1. Would disclosure of information obtained put participants at risk for civil or criminal liability or damage to their financial standing, employability or reputation? [ ]  Yes [x]  No

*If the answer to b and c is Yes, the research is not eligible for this exemption. Do not proceed.* *Use the standard CMU IRB Application.* |
| **6. Protocol Description** |
| Provide, in lay terms, a summary of your proposed study as outlined below. You may attach the protocol to this form if you like. |
| Purpose of the study. To learn what children in grades three through five know about architecture |
| Describe the research procedures (include the activity, location and time required of the participant). Subjects will be administered a paper and pencil test at the subjects' school with the PI and/or Co-PI and school teacher(s) present in the classroom. Test is expected to take subjects approximately 20 minutes to complete. Specific questions are not yet determined, but will focus on three areas of architectural knowledge: 1) What does an architect do?2) Visual literacy (ability to “read” a building and/or context)3) Mapping skills  |
| Who will be asked to participate? Subjects will be third, fourth, and fifth graders at two Pittsburgh Public Schools: Lincoln Academy and Carmalt Academy. |
| Will tasks be done on a computer? [ ]  Yes [x]  No If yes, how will the tasks be accessed? [ ]  Remotely via the internet? [ ]  In the research lab? [ ]  Other, please explain:       |
| Will the research be conducted on the CMU campus? [ ]  Yes [x]  No If no, please indicate the location(s). at the subjects' schools (Lincoln and Carmalt Academies) |
| **7. Participants** |
| *Research including prisoners is not eligible for exempt status. Research with minors is only eligible if it’s an education test, is done in an educational setting or it is only observation of public behavior.*  |
| How many participants are needed for the study? ??? UNSURE PLEASE ADVISE. ??? |
| What is the age range of participants in the proposed study? 8-11 |
| What will the ratio of males to females be? Approximately 1:1 |
| What percentage will be from minority groups? Lincoln Academy is 98% African American, Carmalt is 45% African American. |
| Please provide inclusion and exclusion criteria:  Inclusion: in third, fourth, or fifth grade at Lincoln or Carmalt Academy, Exclusion: subject declines to participate. |
| **8. Participant Recruitment** |
| Describe how participant recruitment will be performed. Include how and by whom potential participants are introduced to the study *(check all boxes below that apply).* Subjects will be identified by the school as currently enrolled in third, fourth, or fifth grade.  |
| *Check all boxes below that apply.* |
| [ ]  CMU directory | [ ]  Postings, Flyers | [ ]  Radio, TV |
| [ ]  E-mail solicitation Indicate how the email addresses are obtained:      |
| [ ]  Web-based solicitation. Specify sites:       |
| [ ]  Participant Pool. Specify what pool:       |
| [x]  Other, please specify: Through the schools. |
| *Please attach any recruiting materials you plan to use, including an introductory script and the text of e-mail or web-based solicitations you will use. Note: the introductory script is used in lieu of a consent form.*  |
|  **9. Participant Compensation and Costs** |
| Are participants to be compensated for the study? [ ]  Yes [x]  No If yes, what is the amount, type and source of funds? |
| Amount**:**  | Source:       | Type:       |
| Will participants who are students be offered class credit? | [ ]  Yes [ ]  No [x]  NA |
| How will you facilitate payment to participants without linking them to study data?       |
| Are other inducements planned to recruit participants? [ ]  Yes [x]  No If yes, please describe.       |
| Are there any costs to participants? [ ]  Yes [x]  No If yes, please explain.       |
| **10. Risks and Benefits**  |
| Will participants receive intangible benefit from the study? [ ]  Yes [x]  No |
| Discuss the direct and indirect benefits to participants. none |
| Discuss the risks to participants.  none |
| Discuss how any risks will be managed and/or minimized.       |
| If deception is involved, please explain.       |
| **11. Confidentiality and Data Security** |
| Will personal identifiers be collected? [x]  Yes [ ]  No | Will identifiers be translated to a code? [ ]  Yes [x]  No |
| Will recordings be made (audio, video)? [ ]  Yes [x]  No If yes, please describe.   |
| Who will have access to data (surveys, questionnaires, interview records, etc.)?  PI, Co-PI, faculty advisor, potential use in dissertation |
| Describe how you will protect participant confidentiality and secure research records (Will they be stored on a secure computer, locked cabinet, etc?).  As the test being administered is a paper and pencil test, the first page will have identifying information on it. Once the test has been completed, identifying information will be translated into code and placed on the second page of the test. The first page of the test with identifying information will be removed from the test and destroyed. Additionally, the data collected will be stored on a password protected university computer for electronic files or in a locked cabinet for paper files. |
| Describe your process for monitoring data to ensure that study goals are met. (Review of lab notebooks, meetings to review data, etc.) PI and Co-PI will meet to review data and report to faculty advisor. |
| **12. Conflict of Interest** |
| Do you or any individual who is associated with or responsible for the design, the conduct of or the reporting of this research have an economic or financial interest in, or act as an officer or director for any outside entity whose interests could reasonably appear to be affected by this research project: [ ]  Yes [x]  No If yes, please provide detailed information to permit the IRB to determine if such involvement should be disclosed to potential research subjects.       |
| **13. Cooperating Institutions** |
| Is this research being done in cooperation with any institutions, individuals or organizations not affiliated with CMU? [ ]  Yes [x]  No If yes, please list.       |
| Have you received IRB approval from another IRB for this study? [ ]  Yes [x]  No [ ]  PendingIf yes, please attach a copy of the IRB approval.  |
| If applicable, please provide the name(s) and address(es) of all officials authorizing to access human subjects in cooperating institutions not affiliated with CMU.       *Please attach documentation of approval.* |

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| **Principal Investigator’s Assurance Statement for Using Human Subjects in Research** |

I certify that the information provided in this IRB application is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of IRB approved studies, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the studies protocol and any stipulations imposed by Carnegie Mellon University Institutional Review Board.

I understand that it is my responsibility to ensure that the human participants’ involvement as described in the funding proposal(s) is consistent in principle, to that contained in the IRB application. I will submit modifications and/or changes to the IRB as necessary.

I agree to comply with all Carnegie Mellon University policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research, including, but not limited to:

* Ensuring all investigators and key study personnel have completed human subjects training program;
* Ensuring protocols are conducted by qualified personnel following the approved IRB application;
* Implementing no changes in approved IRB applications without prior IRB approval in accordance with CMU IRB policy (except in an emergency, if necessary to safeguard the well-being of a human participant, and will report to the IRB within 1 day of such change);
* Informing participants of any relevant new information regarding their participation in the research that becomes available.
* Promptly reporting to the IRB any new information involving risks to research participants, including reporting to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research.
* If unavailable to conduct research personally, as when on sabbatical leave or vacation, arrangements for another investigator to assume direct responsibility for studies will be made through modification requests to the IRB;
* Promptly providing the IRB with any information requested relative to protocols;
* Promptly and completely complying with IRB decisions to suspend or withdraw approval for projects;
* Obtaining Continuing Review approval prior to the date the approval for a study expires (approval for the study will automatically expire);
* Maintaining accurate and complete research records, including, but not limited to, all informed consent documents for 3 years from the date of study completion;
* Informing the CMU IRB of all locations in which human participants will be recruited for protocols and being responsible for obtaining and maintaining current IRB approvals/letters of cooperation when applicable;
* Complying with federal, state and local laws and regulations and sponsor terms and conditions; and
* Complying with CMU policies on the responsible conduct of research.

 Kelly S. Lyons

Principal Investigator Name and Signature Date

*Note: If e-mailed from the PI’s CMU e-mail account a hand written signature is not needed. Please type in name and date.*

*If the PI is a student, the faculty advisor must submit a Faculty Advisor Assurance Form.*

**Please email all documents to** **irb-review@andrew.cmu.edu****.**

Note: Links to the policies and Federal regulations for the protection of human research subjects (including the Code of Federal Regulations [.CF.R.] Title 45 CFR Part 46, and Title 21 C.F.R. parts 50 and 56) are available on the IRB web page (<http://www.cmu.edu/provost/spon-res/compliance/hs.htm>).

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| **Comments:**  |