**Research Integrity**



Alumni Memorial Building

27 Memorial Drive West

Bethlehem, PA 18015

(610) 758-2871 *http://www.lehigh.edu/irb*

**Amendment/Modification Form**

**For Previously Approved Studies**

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| **Study Title:** |
| The Effort Economy |

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| **Research Personnel:**  Only Lehigh University faculty may serve as P.I. Please see the Lehigh University [Principle Investigator Policy](https://research.cc.lehigh.edu/sites/research.cc.lehigh.edu/files/documents/ORSP/05-Dec-2017 Human Subjects Research PI.pdf) on the [IRB website](http://research.cc.lehigh.edu/irb) for more information. | | | | | | |
| **P.I.’s Name:** | Catherine M. Arrington | | | | |  |
| **Additional personnel:**  Please list anyone involved in the design, conduct, or reporting of the human subjects research proposed in this application: | | | | | |  |
| David Braun | | **Lehigh Faculty** | **Lehigh Student** | **Lehigh Staff** | **Other (specify):**   Lehigh Post Doc |  |
|  | | **Lehigh Faculty** | **Lehigh Student** | **Lehigh Staff** | **Other (specify):** |  |
|  | | **Lehigh Faculty** | **Lehigh Student** | **Lehigh Staff** | **Other (specify):** |  |
|  | | **Lehigh Faculty** | **Lehigh Student** | **Lehigh Staff** | **Other (specify):** |  |
| **Additional names:** | | | | | |  |

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| **Conflict of Interest (faculty and staff only – not required for students)**  [Significant Financial Interests](https://research.cc.lehigh.edu/coi-glossary" \l "significant-financial-interest) [Related](https://research.cc.lehigh.edu/coi-glossary" \l "related) to research must be disclosed in accordance with the [Lehigh University policy on Conflicts of Interest Related to Research and Sponsored Programs](https://research.cc.lehigh.edu/sites/research.cc.lehigh.edu/files/documents/ORSP/Policies/22-Jan-2021 Policy fCOI Related to Research and Sponsored Programs.pdf). |
| **Do any [Project Personnel](https://research.cc.lehigh.edu/coi-glossary" \l "project-personnel) have [Significant Financial Interests](https://research.cc.lehigh.edu/coi-glossary" \l "significant-financial-interest) [Related](https://research.cc.lehigh.edu/coi-glossary" \l "related) to the research described in this application that require disclosure pursuant to the** [**Lehigh University policy on Conflicts of Interest Related to Research and Sponsored Programs**](https://research.cc.lehigh.edu/sites/research.cc.lehigh.edu/files/documents/ORSP/Policies/22-Jan-2021 Policy fCOI Related to Research and Sponsored Programs.pdf)**?**  **No**  **Yes:**  Name of Project Personnel with Significant Financial Interests to disclose:  Has the disclosure already been submitted to either ORSP, VPR, or Research Integrity?  **No**  **Yes** |

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| **Study Description:** | | | | | |
| **Master’s Thesis** | **Dissertation** | | **Other Graduate Student Project** | | **Undergraduate Senior Thesis** |
| **Other student (Graduate or Undergraduate) Project:** | | | | | |
| **Non-Sponsored Research** | | **Sponsored Research (list sponsor):** | | **Currently unfunded but future funding is anticipated (list sponsor):** | |
| **Other Details (check all that apply):** | | | | | |
| **Research where a student/fellow is supported via a federal training grant or other federal funding** | | | | | |
| **Research that involves federal personnel or involvement of/support from the Department of Veterans Affairs** | | | | | |
| **Research covered by an NIH-issued Certificate of Confidentiality (CoC)** | | | | | |
| **Research that involves obtaining information from student [education records](https://research.cc.lehigh.edu/irb-glossary" \l "education-records) subject to the** [**Federal Education Rights and Privacy Act (FERPA)**](https://research.cc.lehigh.edu/node/303) | | | | | |

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| **Additional Items Required for Review of the Amendment/Modification if New or Revised:** | |
| Informed Consent documents/assent scripts | Instruments (Surveys, tests, etc.) |
| Letter of Approval (for research conducted in school or other institutional setting) | |
| Recruitment materials (emails, flyers, advertisements, scripts, etc.) | |
| Other (specify): | |

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| **Progress Report:**  Please provide the following information regarding your previously approved study | | |
| **1. Please describe the status of the originally approved research in regard to collecting, analyzing, and publishing the data. Your response should address the following questions: Are you still recruiting subjects? Are you still collecting data?** | | |
|  | The research covered under this IRB protocol is still being conducted. I am launching new studies this spring that are within the guidelines of what I have outlined under my previous proposal. |  |
| **How many subjects have enrolled/participated in your approved study to date?** | | |
|  | ~500-1000 |  |
| **How many more subjects do you intend to enroll/invite to participate in your study after the proposed modification is approved?** | | |
|  | About 200 |  |
|  |  |  |
| **Proposed Modification/Amendment:**  Please provide the following information regarding your proposed changes. | | |
| **2. Please describe the proposed modification(s) to the original approved study. *NOTE: Please submit any revised forms, questionnaires or instruments with your IRBNet package.*** | | |
|  | I wish to include scales / surveys that assess people’s relationship to mental effort. At this time, I am proposing to include the need for cognition scale, developed in 1982 by John Cacioppo and colleagues. This particular survey has over 7500 citations and is one of the most popular surveys for assessing the extent to which people seek out mental effort in their daily lives. I included in the package an image of the survey for easy access, as well as the PDF to the source paper.  I would ideally like this amendment to be broad enough to encompass similar such surveys should I choose to add them in the future, so I wouldn’t need to file an amendment each time I wish to add one. If it is better that I file a unique amendment each time I wish to add a survey, however, I can certainly do so. |  |
| **3. Will the proposed modification change your recruitment procedures?**  **Yes**  **No**  **If yes, describe the changes.** | | |
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| **4. Will the proposed modification include a change in the characteristics of the subjects you want to recruit?**  **Yes**  **No**  **If yes, describe the change(s)** | | |
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| **5. Will the informed consent process change as a result of the modification(s)?**  **Yes**  **No**  **If yes, please describe the changes to the informed consent procedures and attach a copy of the new informed consent or the additional informed consent form to the package.** | | |
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| **6. Will the procedures for maintaining the anonymity or confidentiality of the data change?**  **Yes**  **No**  **If yes, describe the nature and extent of the changes to the procedures for protecting the data.** | | |
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| **7. Have you received any complaint regarding any part of your procedure or its results from a subject that has not been previously reported to the committee?**  **Yes**  **No**  **If yes, describe the nature and extent of any measures taken.** | | |
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| **8. Have any subjects withdrawn from the previously approved study?**  **Yes**  **No**  **If yes, please describe the situation under which the subject withdrew and give the reason, if known.** | | |
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