

**University of Kansas**

**Human Research Protocol**

**For Use with** [**eCompliance**](http://ecompliance.ku.edu/) **Only**

# PROJECT INFORMATION

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| **Project Title** | A dynamic latent class model to identify inattentive responders who do not follow instructions |
| **Investigator Name** | Holger Brandt |
| **Faculty Supervisor (Students Only)** |  |

This form must be used to submit an application through the eCompliance system.

**No other methods of submission will be accepted.**

Access the system here: [ecompliance.ku.edu](http://ecompliance.ku.edu/)

For faster processing, ensure all study staff have all completed the required [Human Research Training](https://www.citiprogram.org/Shibboleth.sso/Login?target=https%3A%2F%2Fwww.citiprogram.org%2FSecure%2FWelcome.cfm&entityID=https%3A%2F%2Fshibidp.ku.edu%2Fidp%2Fshibboleth).

Contact [irb@ku.edu](mailto:irb@ku.edu) with any questions!

# 1. Subject Information

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| **1.1 Number of Subjects**: |

1000

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| **1.2 Subject Age (*Check all that apply*)** |

0-7

8-17

18-65

65+

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| **1.3 Special Populations (*Check all that apply)*** |

Minors

Non-English speaking

Mentally or developmentally disabled individuals

Pregnant Women

Prisoners

Individuals with diminished capacity for consent

Individuals with a Legally Authorized Representative

Other vulnerable population (describe below)

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| **1.4 Describe any specific populations targeted for inclusion or exclusion.** |

There are no specific populations targeted for inclusion or exclusion.

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| **1.5 Describe target demographics of proposed subjects; explain how you will ensure that selection is equitable and that all relevant ethnic groups, genders, and populations have access to the study.** |

Participants will be of any gender and any race and over the age of 18.

# 2. RECRUITMENT

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| **2.1 Describe the recruitment process for the study. Explain how you will gain access to and recruit the subjects for participation in this project.** |

Participants will be recruited through Amazon’s Mechanical Turk system.

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| **2.2 Identify any cooperating institutions by name.** |

NA

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| **2.3 External Study Team Members** |

**External study team members (individuals NOT currently affiliated with KU) will collaborate on this project.**

**If yes, explain external study team member’s roles in the projects. Explain if they will be involved in a) obtaining consent of participants, b) interacting or intervening with participants, or c) have access to identifiable data.**

Click here to enter text.

**External study team member’s home institution has an Institutional Review Board that is currently registered with OHRP**

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| **2.4 Where will the research activities take place? List all off campus locations. Explain if this study will take place at more than one location/institution.** |

Fraser Hall on the KU Lawrence campus is where the technical implementation of the experiment will happen. The experiment is an online experiment.

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| **2.5 Identify all applicable recruitment methods.** |

Flyers

Letter

Telephone

Newspaper

Poster

Departmental Communication

Purchased sample list

Personal or Professional contacts

Internet

E-mail

Amazon Mturk

Social Media

SONA

Third party (Professional or Charitable Organization)

Other

***\*\*Please upload copies of materials in the "Recruitment Documents" section in eCompliance.\*\****

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| **2.6 Are you recruiting students from a class you teach or for which you have a responsibility?** |

**No**

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| **2.7 Are you recruiting employees who directly or indirectly report to you?** |

**No**

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| **2.8 If yes to 2.6 or 2.7, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.** |

NA

# 3. COMPENSATION

**Subjects will not receive compensation**

**Students will receive extra credit or course credit**

**Subjects will receive monetary compensation**

**Subjects will receive another form of compensation.** *Please explain in 3.1*

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| **3.1 Describe the compensation or credit, including amount, scheduling, and method (e.g. ClinCard). Explain what will happen if subjects withdraw from the study.** |

Each participant will receive $1 for participating in the study and an additional $2 bonus pay for completing the study. If subjects decide to withdraw from the study before completing it they will still receive the $1. If they withdraw from the study after completion they will also keep the $2 bonus.

By checking this box, I understand that the HRPP is NOT granting approval for a specific method of payment and that I may need additional fiscal approval from the Office of Fiscal Affairs in order to pay research participants (Contact Kevin Teel @ 864-7775 for questions about participant payment).

***\*\*Drawings and raffles may not be permitted for payment or recruitment; See HRPP website for detailed guidance.\*\****

# 4. PROJECT INFORMATION

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| **4.1 Expected study time period.** |

**From**: 09/2018

**To**: 12/2018

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| **4.2 Do you currently have funding or expect to obtain funding in the future?** |

I applied for the New Faculty General Research Fund of KU (NFGRF). The proposal is pending.

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| **4.3 Select type of funding.** |

University (NFGRF, Graduate Schoo, etc.)

**If yes to 4.3, what is your award’s current status?**

Proposal

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| **4.4 Describe the purpose of the research. Explain what is intended to be discovered; include goals, aims, and objectives and/or state the hypothesis to be tested.** |

The investigator developed a model that can identify inattentive responses based in a dynamic latent class framework. He plans to collect data in an online experiment using Amazon's Mechanical Turk that includes conditions of standard instructions, warning instructions (to keep participants attentive), and instructions that are used to create inattention. The item pool includes 100 items on 10 personality facets. The scope is to test if the developed statistical method is able to identify the inattentive behavior. The investigator hypothesizes that about 5% of the participants in the control condition will be inattentive, fewer in the warning condition, and most of the participants in the two treatment conditions. He further hypothesizes that his model can detect this inattentive behavior and the time of its occurrence (without the knowledge of when or to who the instruction to show inattentive behavior has been presented).

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| **4.5 Research Topic Background: Provide a brief scientific or scholarly background for the research activities, address gaps in current knowledge.** **\*\*Please include background information of your research topic. Do not submit personal background or resume/CV information.\*\*** |

The development of new methods that can better identify inattentive behavior is extremely important. Particularly, these situations can occur in settings like Mturk experiments where participants might become inattentive because they are want to finish the survey as fast as possible. If such behavior occurs, the collected data is contaminated with responses that do not relate to the questions or items. This will produce severe bias in any statistical analysis that ignores the existence of inattentive behavior. So far, methods could only identify inattentive persons per se and assumed that their behavior did not change during the testing situation (e.g., persons started unmotivated and did not change during the testing). This assumption is implausible and results in artifacts if persons actually change their behavior during the testing procedure. The investigator developed a new method that overcomes these limitations and provides a more plausible model for human behavior. The method is based on a dynamic latent class structural equation modeling framework and is implemented using a Bayesian estimator. It will be the first time that dynamic changes of attention in testing situations is identifiable. If the experiment is successful it will open up many new opportunities in data analysis and experimental design (e.g., by providing feedback to the participants during the testing if they become inattentive).

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| **4.6 The revised Common Rule definition of a “Clinical Trial” is the following:** *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.*  **Does your study meet the definition for a “Clinical Trial?”** |

No

# 5. RISK & BENEFITS

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| **5.1 Does this study involve any of the following? (*Check all that apply*)** |

Deception

Omission

Misleading information/false feedback

Physical or mental stress

Collection of fluids or tissue

Genetic information

Substances taken internally or applied externally

Mechanical or electrical device applied to subjects

Information pertaining to illegal activity

Information pertaining to substance use

DXA Scan, X-RY, MRI

Information relating to sexual attitudes, orientation or practice

Private identifiable information

Personal or sensitive information

Private records (academic or medical)

Social or economic burden to participants

Exposure to hazardous materials

Information that if released could damage an individual’s financial standing, employability, reputation, or cause social stigmatization or discrimination

Other

None of these

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| **5.2 Describe the nature and degree of the risk or harm checked above. If using deception or omission, include a justification for the deception or omission.** |

The instruction will only include information that persons will respond to items related to personality facets. It will not provide a priori the information that the actual scope is attention/inattention because this might affect persons such that they might show a different behavior than they would do in other online experiments. A debriefing (supporting documents) will provide the information about the statistical model and the scope of the experiment (identify when and if persons start to be inattentive).

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| **5.3 What steps will be taken to minimize the risks or harm and to protect the subject’s welfare (when risk is greater than minimal)?** |

The investigator does not expect more discomfort than participants would experience in everyday life. The items chosen are standard items in personality research (see item list in supporting documents). The omission that we will use a method that distinguishes between attentive and inattentive behavior will not affect the participants because no individual identifier will be used.

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| **5.4 Describe the anticipated benefits of the research for individual subjects.** |

The participants will have an experience about being involved in applied research and problems associated with data collection (inattention). Contrary to many experiments, this experiment focuses on the development of a statistical method, participants learn about the basic idea of how that works (debriefing statement). They also learn more about themselves because the items target personality facets, which might let participants reflect more about themselves.

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| **5.5 Describe the anticipated benefits of the research for society or science, and explain how the benefits outweigh the risks.** |

The new model will help to collect better data that does not suffer from contamination and responses that do not relate to the questions or items in the experiment. This will enhance the validity of finding in social and behavioral sciences in general. It can also help to increase possibilities to collect data, for example, if persons who show inattentive behavior can be reinforced to change again to attentive behavior. This will be important, for example if questionnaires are used in longitudinal treatment studies. Hence, subjects’ participation will benefit society by adding to the scientific knowledge base in this field.

# 6. DATA COLLECTION & SECURITY

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| **6.1 Data Collection & Security** |

Observation

Interviews

Focus groups

Surveys/Questionnaires

Psychological tests

Educational tests

Internet based methods

Blood draw, saliva swabs, or other biological sampling

Tissue biopsies

Audio recording

Video recording

Previously collected data (no individual identifiers)

Previously collected data (with individual identifiers)

Other

***\*\*Upload all data collection documents (surveys, specimen protocols, interview questions, etc) in the eCompliance "Supporting Documents" page.\*\****

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| **6.2 Procedures (Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Include a time line or step by step listing.)** |

The experiment will be implemented in Amazon’s Mturk. First, a consent form will be presented (see supporting documents), with the instruction to read and click an accept button if they consent. After that a short instruction will be presented stating that they will respond to questions relating to personality facets (see supporting documents). 25% of the participants will have an additional information that the investigators implemented a new statistical method to detect inattentive behavior (warning condition). Then, participants will respond to 100 personality items (in a randomized sequence) and two bogus items. During the testing, 50% of the participants will receive an additional instruction after a randomly programmed time point (e.g., after item 22 for one subject and item 56 for another one). The new instruction asks the participants to answer inattentively to the remaining items (either covert or outright). At the end of the items, participants will answer some basic demographic information, and a questions on their strategy if they were inattentive. After completing this part a debriefing statement will be shown to the participants that explains the research goal on inattention (see supporting documents), the participants will be informed that they can decide to withdraw from the study, and receive their monetary compensation.

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| **6.3 Sharing the results with Subjects or Others. (Indicate if results like tests or incidental findings will be shared with the subject or others and if so, indicate how it will be shared.)** |

Not shared.

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| **6.4 Withdrawal of Subjects (Describe the procedures to be followed when subjects withdraw from research or under what circumstances subjects may be withdrawn without their consent.)** |

Participants can decide to end the questionnaire before finishing and they will still receive the $1 participation compensation.

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| **6.5 Protected Data to be Collected (*Check all that apply*)** |

Protected Health Information

Unique ID number (e.g. employee/student ID, driver’s license number)

Academic records

Social Security Number

Other personally identifiable information

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| **6.6 Describe the steps that will be taken to secure the data during storage, use, and transmission. How and where will the data be stored, for how long will it be kept, what safeguards are in place for data with identifying information. Include a description of physical and electronic security.** |

Data will be stored on a KU computer located in the investigators laboratory. The room is locked. The computer is password secured and follows the standards of KU’s IT security software that is regularly updated. For the data storage an external hard drive will be used that will be securely locked in a shelf in the investigators (locked) room. No identifying information will be collected.

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| **6.7 Identify any direct identifiers like name, unique identifier, address, e-mail, etc. that will be kept with the records. Explain why it is necessary to record the identifiers and describe the coding system to be used.** |

none

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| **6.8 If retaining a link between study code numbers and direct identifiers after data collection is complete, please explain why this is necessary, how long the link will be kept, and how it will be stored.** |

NA

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| **6.9 If using audio and video recording, describe how the recordings will be used, how confidentiality will be maintained, and how and when the recordings will be destroyed or completely deidentified.** |

NA

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| **6.10 As part of the study will you:**  **a. Obtain protected health information (PHI) from a third party (such as a hospital or doctor's office)**  **b. Have access to PHI in the subject's records?**  **If yes to either a or b, please describe how you will satisfy the HIPAA requirements for authorization to use PHI in research below. (Submit the Statement on Use of Protected Health Information (PHI) form)** |

This study will not collect protected health information.

# 7. INFORMED CONSENT

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| **7.1 Specify the type of informed consent you will use with this research project.** |

***\*\*Consent form templates can be found on the HRPP website. Please upload all consent form drafts to the "Consent Form" section in eCompliance.\*\****

Signed Consent

Type of Consent

Adult

Parent/Guardian

Assent Script/Procedures

Foreign Language version

Oral Consent ([Waiver of documentation of consent](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-30), upload script in eCompliance)

A signed consent form would be the only record linking the subjects to the research, and the principal risk of signing a consent form would be potential harm resulting from a breach of confidentiality

The research presents no more than minimal risk of harm to subjects and involves no

procedures for which written consent is normally required outside the research context

Information Statement

Debriefing Statement

Waiver of Consent is requested

See OHRP [waiver of consent](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-22) FAQs. The following conditions must be addressed:

1) the research involves no more than minimal risk to the subjects;

2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

3) the research could not practicably be carried out without the waiver or alteration;

4) whenever appropriate, the subjects will be provided with additional pertinent information after participation)

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| **7.2 Describe any potential concerns with obtaining informed consent (Foreign language, minimizing possibility of coercion, etc.)** |

To minimize the possibility of coercion, the informed consent will notify participants that they may withdraw at any time. There are no other potential concerns with obtaining informed consent.

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| **7.3 Describe the process you will follow to obtain consent and/or assent. Include names of individuals on the research team who will obtain consent, where and when the process will take place and how you will ensure the subject’s understanding.** |

The very first page of the study will include the consent form. Participants will be asked to read this form and check a box at the bottom of the page to show they are giving consent to participate. This fully ensures no personal information will ever be linked the data collected. Participants will be made aware that they can print a copy of the consent form for their records.