

The following sample application is intended for educational purposes and to help guide you in the development of your application. It is important to remember that every project is unique and different ethical or regulatory elements may apply and as such, procedures that are appropriate for this project may not be appropriate for others.

Additional comments are signified by the following symbol to the right.

- ➔ To view the comments, simply click the symbol.
- ➔ These additional comments include useful tips.



Some items in this application that will stand out to you include:

- All materials are easily understood by the layperson.
  - Tip- consent forms that are difficult to understand or are missing essential elements will delay IRB approval.
  - Tip- have a friend review your application and consent form to provide feedback on its readability.
- The investigators ensured that spelling and grammar are correct and also ensured the use of complete sentences.
  - Tip- applications that are difficult to understand are one of the most common delays to IRB approval. The IRB sometimes finds itself requesting “editorial” changes in order to move forward with a review of the regulatory and ethical components of a study.
- All of the questions are answered.
  - Tip- answering the question doesn’t only mean providing a response, it also means providing a response that addresses the information that is requested.
- All of the appendices, instruments, consent materials, recruitment scripts, and CITI certificates (redacted) were included at the time of initial submission.
  - Tip- it is not uncommon to receive applications lacking supporting documents.
- The study is properly described as confidential throughout the entire application.
  - Tip-
    - Confidential refers to data collection that can be linked to an individual subject but is kept private (interviews must always be described as confidential!).
    - Anonymous refers to data collection that cannot be linked to individual subjects.
- The application, recruitment script and consent form consistently describe the project.
  - Tip- the application, consent and recruitment script should all be congruent – this includes a consistent description of the procedures, time of participation, risks and benefits, and nature of the data (anonymous or confidential).
- Risks and benefits are carefully assessed (section 5).
  - Tip- it is important to carefully consider and disclose all potential risk to subjects.
  - Tip- do not overstate the benefits.
- Psychological discomfort is identified as a risk and participants are provided counseling referral information as part of the consent and debriefing process.
  - Tip- if you are going to ask questions that may induce distress, you should provide appropriate referral information to participants.

## Use of Human Subjects in Research Application



(LEVEL II or LEVEL III projects)

THIS SECTION FOR USE BY IRB		IRB LOG # [REDACTED]	
Name of discipline -specific reviewer: [REDACTED]		Date Received by Office of Research Compliance:	6/30/15
Level of review (please choose either Expedited or Full board) <input checked="" type="checkbox"/> <b>Level II – Expedited Review</b> <i>Please specify one or more category:</i> <input type="checkbox"/> - #1 - Clinical Studies <input type="checkbox"/> - #2 - Collection of Blood Samples <input type="checkbox"/> - #3 - Pros collection of Bio Specimens <input type="checkbox"/> - #4 - Data through non-invasive procedures. <input type="checkbox"/> - #5 - Materials (Data, documents, records or specimens collected for non-research purposes) <input type="checkbox"/> - #6 - Data from voice, video, digital or image recordings <input checked="" type="checkbox"/> - #7 - Individual or group characteristics		Agenda date:	
		Date of Log # notification email:	
		Date of Final Approval:	
		Reminder of Annual review email:	
<input type="checkbox"/> <b>Level III – Full Board Review</b> <i>Reason:</i>			
Signature of IRB Chairperson		Signature of IRB Admin. or Designee	
Date		Date	

### INSTRUCTIONS FOR INVESTIGATORS:

- Submit this completed document with any needed attachments via email attachment to an [IRB discipline specific reviewer](#).  
 To submit the form with a typed signature, the form must be submitted from the Investigator's @kent.edu email account. If completed form is signed and then scanned as a PDF attachment, the @kent.edu email requirement does not apply.  
 Submission of incomplete forms or failure to include all of the needed attachments will most likely result in delays for IRB review/approval. Handwritten forms are not accepted.  
**\*\*Single left-click to complete text fields. To check a box, double left-click on the box, then click "checked". Click OK.**
- Do NOT begin data collection prior to receiving notification from the KSU IRB that the study has received final approval.

### Section 1 – TITLE & PRINCIPAL INVESTIGATOR (PI) INFORMATION

Title of Study: <b>Perfectionism, Mindfulness, and Negative Affect &amp; Mood</b>		
Estimated begin and end dates for the project		<b>September 2015</b> to <b>January 2016</b>
Name: [REDACTED]		Status: <input checked="" type="checkbox"/> Faculty <input type="checkbox"/> Staff
Phone: [REDACTED]		Department: [REDACTED]
Purpose of Research	<input type="checkbox"/> Faculty Research <input checked="" type="checkbox"/> Student Thesis/Dissertation → Complete <a href="#">Appendix A</a>  <input type="checkbox"/> Other: Specify: [REDACTED]	PI Email: [REDACTED]@kent.edu
Email address(es) for others that should be notified regarding the status of this application (i.e., student(s) conducting research, program administrators, etc.):		[REDACTED]@kent.edu [REDACTED]@kent.edu

*Only faculty members and professional staff who are full-time university employees are eligible for PI status. Students conducting research for their dissertation or master's thesis research can still have primary responsibility for the intellectual content, conduct of the research, or primary authorship in publications by serving as co-investigators or key personnel on IRB applications. If you are a KSU employee conducting research involving human subjects as part of your graduate or undergraduate program, your faculty advisor must serve as the PI of record for IRB protocols. [Please review IRB policy for PI eligibility and responsibilities.](#)*


- a. Are there any Kent State University affiliated co-investigators or key personnel on this protocol?

*"Key personnel" are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals, who recruit participants, obtain consent or, who collect study data. Students conducting research for their dissertation or master's thesis research can still have primary responsibility for the intellectual content, conduct of the research, or primary authorship in publications by serving as co-investigators or key personnel on IRB applications.*

☒ Yes → Complete [Appendix A](#)   
☐ No


- b. Are there any external (non-Kent State University affiliated) co-investigators or key personnel *engaged* in the research?

*"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Kent State University. See [OHRP Engagement Guidance](#) or contact [ORC](#) for more information.*

☐ Yes → Complete [Appendix B](#)   
☒ No

- c. Has the Principal Investigator (PI) completed the required web-based course years (CITI, or equivalent) in the protection of human research subjects?

*Educational requirements (initial and continuing) should be satisfied prior to submitting the application for IRB review. See [Human Subjects Protection Training policy](#) for more information. Final approval from the IRB will not be obtained until all requirements are fulfilled.*

☒ Yes → Attach **Copy of completion certificate**   
☐ No

- d. Are there other person(s) (e.g., research manager, study or regulatory coordinator, research assistant, etc.) that we should contact if further information about this application is needed?

☐ Yes  
☒ No

If Yes → Name:

Phone:

Email:

## Section 2 – FUNDING INFORMATION

- a. Does this research have external funding or have you requested external funding for this research?

☐ Yes  
☒ No

If Yes → Specify sponsor:

Protocol/Proposal #

Institution (if not KSU):

Have all Kent State University investigators and key personnel completed the required COI disclosure for externally funded research for the purposes of this research project?

☐ Yes  
☐ No

- b. Is any support other than monetary (e.g., drugs, equipment, supplies, etc.) being provided for the study?


☐ Yes  
☒ No

If Yes → Specify support and provider:

Attach a copy of the grant application or funding proposal. 


*The university is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded. If the research funded by a federal agency and involves a subcontract to or from another entity, an [IRB Authorization Agreement](#) may be required. Contact the [Office of Research Compliance \(ORC\)](#) for more information.*

- c. Does the PI for this research or their immediate family members (*i.e., spouse, domestic partner, or dependent children*) have a financial interest that would reasonably be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?

☐ Yes → Complete  
[Appendix Z](#)   
☒ No

*Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).*


- d. Does the PI for this research or their immediate family members (*i.e., spouse, domestic partner, or dependent children*) have a non-financial Conflict of Interest that would reasonably be affected by the research

☐ Yes → Complete  
[Appendix Z](#)   
☒ No

*A non-financial conflict of interest is an interest, other than monetary, of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with the obligation to protect research participants and potentially compromises the objectivity and credibility of the research process.*


### Section 3 – RESEARCH DESIGN

- a. Will research activities be conducted at a site where approval from an additional IRB (other than KSU IRB) is needed?

☐ Yes → Complete  
[Appendix O](#)   
☒ No

*In some cases research conducted at locations other than Kent State University (i.e., other universities, hospitals, prisons) may require another institution's IRB approval, a letter of support (as in the case of elementary or high schools), or the execution of an IRB Authorization or Individual Investigator Agreement. See [OHRP Engagement Guidance](#) or contact ORC for more information.*

- b. Is any of this research being conducted outside of the U.S.A?

☐ Yes → Complete  
[Appendix U](#)   
☒ No

- c. Briefly summarize the purpose of the proposed research using **non-technical** language that can be readily understood by someone outside the discipline. **Use complete sentences (limit 300 words).**

This research will test the relationship between the constructs of perfectionism, mindfulness, and the experience of psychological distress or depressive symptoms. Perfectionism may be considered a multidimensional construct, with some aspects that can be considered maladaptive and socially driven, or more adaptive and internally driven. Research has found that maladaptive aspects of perfectionism can present as a precursor to psychological distress, and to experiences of depression and anxiety, particularly if the individual is prone to rumination of a brooding, rather than reflective, nature (Blankstein & Lumley, 2008; Flett et al., 2002; Flett et al., 2011; Harris et al., 2007; Nepon et al., 2011; O'Connor et al., 2007; Olson & Kwon, 2008). The tendency to ruminate, rather than reflect or "look back", on personal events has been tied to experiences of depression and depressive symptoms, and anxiety, among several other forms of psychological discomfort, such that those who ruminate are at a higher risk of experiencing such discomfort (e.g., Nolen-Hoeksema, 1991; Nolen-Hoeksema et al., 2008). Research has also suggested the presence of a relationship between brooding rumination, distress and depressive symptoms, and mindfulness, in that individuals are less likely to ruminate if they are taught mindful awareness strategies, or are prompted to be more aware and accepting of their circumstances, indicating that mindfulness, or the act of being mindful, may serve as a "buffer" for those at risk for depression (e.g., Segal et al., 2002; Teasdale et al., 2000; Teasdale et al., 2002). There is scant research on how the tendency to be mindful, or trait mindfulness, may interact with different facets of perfectionism in the production or prevention of psychological distress. For this reason, we will be testing whether trait mindfulness interacts with perfectionism in such a way as to limit psychological distress or depressive symptoms.

- d. List the scientific or scholarly aims of the research study

**The scientific objectives or aims of the study are:**

1. To examine whether perfectionistic individuals exhibit negative changes in affect and levels of distress in response to failure of a task in comparison to non-perfectionistic individuals.
2. To examine whether individuals high in rumination exhibit negative changes in affect and levels of distress in response to failure of a task in comparison to individuals low in rumination.
3. To examine whether individuals low in mindfulness exhibit negative changes in affect and levels of distress in response to failure of a task in comparison to individuals high in mindfulness.
4. To examine whether a potential moderating relationship exists between mindfulness, perfectionism, rumination, and negative affect and distress such that individuals found to be perfectionistic but high in mindfulness report no change or positive changes in affect and levels of distress in response to failure.

5. Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. *Use complete sentences (limit 300 words).*

Research indicates that aspects of perfectionism can contribute to distress and impede psychological functioning; the formation of a *perfectionism diathesis-stress model* suggests that dimensions of perfectionism can act as vulnerability factors to depression and even suicidality, in adults and adolescents, given enough aversive and extant stress (Hewitt et al., 2014; Hewitt & Flett, 1993; Hewitt & Flett, 2002). Perfectionism has also been shown to affect and hinder individuals' responses to brief psychotherapeutic treatments for depression (e.g., Blatt, 1995; 1998).

Although perfectionism is mainly viewed as maladaptive in form, some propose that perfectionism can serve adaptive purposes (e.g., Bieling et al., 2004) and researchers have sought to examine potential coping methods for perfectionists and how they can contribute to or counter psychological distress. Several studies have indicated that rumination of a brooding, rather than reflective nature, may be a maladaptive form of coping for perfectionistic individuals (e.g., Blankstein & Lumley, 2008; Flett et al., 2011; Harris et al., 2007; Olson & Kwon, 2008). Adaptive perfectionism has been found to be associated with positive coping and consciousness (e.g., Enns & Cox, 2002); from this one could suppose that mindful awareness may also aid in productive coping for perfectionistic individuals.

Some research has examined the potential for a fruitful relationship between perfectionism and adaptive coping in the form of mindfulness (e.g., Argus & Thompson, 2008; Hilterman et al., 2012, Short & Mazmanian, 2013; Williams, 2008), but much of the activity has only uncovered correlational relationships. This study would seek to find information about potential causal mechanisms of the relationship, as well as more conclusive information about the construct of perfectionism in itself and its effects over time. Desired results would further understanding about maladaptive and adaptive components of perfectionism, and also further support for more active and mindfulness-based treatments for psychological distress.

6. Identify and describe (in order of occurrence, if applicable) all interventions and interactions that are to be performed solely for the research study. *Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.).*



The experimenter will first provide the participants with general information about the study and the opportunity to present any questions or concerns prior to having them sign informed consent.

Once consent has been signed, the experimenter will, with the help of the participant, hook them up to some psychophysiological equipment. A measure of vagal tone will be obtained from each participant before and during the stressor interview task as a physiological measure of emotion regulation. Vagal tone

will be calculated by utilizing measurements of heart rate variability during respiration. These measurements will be taken using a Biolog device. Three ECG fetropdes from the Biolog device will be attached to the participant in three different locations: the forearm, collarbone, and rib bone. The experimenter will clean the target areas of skin with rubbing alcohol before attaching the fetropdes on the forearm and shoulder bone. The participant will clean the skin and place the fetropde on the rib bone themselves. These ECG fetropdes will measure the milliseconds between each of the participants' heart beats which will be recorded by the Biolog device. Respiration will be measured by a respiration transducer that will be placed around the participants' lower ribs and recorded by the Biolog device. The respiration transducer will fit snugly to adequately measure respiration but loose enough so that the participant is comfortable. This equipment will remain on the participants for the entire duration of the initial portion of the study.

Participants will then be asked to complete the following measures:

- Demographic questionnaire
- Multidimensional Perfectionism Scale (MPS; Hewitt & Flett, 1991)
- Frost Multidimensional Perfectionism Scale (F-MPS; Frost et al., 1990)
- Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006)
- Center for Epidemiological Studies-Depression Scale (CES-D; Radloff, 1977)
- Positive and Negative Affect Schedule, Expanded (PANAS-X; Watson & Clark, 1997)
- Response Style Questionnaire-25 (RSQ-25; Nolen-Hoeksema, 1991)
- State Trait Anxiety Inventory (STAI; Spielberger et al., 1983)
- Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989)
- Psychiatric Epidemiology Research Interview (PERI; Dohrenwend et al., 1978)
- State Rumination Measure (RSQ-15; adapted from Nolen-Hoeksema, 1991)

Next, participants will be instructed to complete two filler manipulation tasks, an anagram task based from word frequency listings (Thorndike, 1921) and upon research findings (Mayzner & Tresselt, 1958) and a set of logical reasoning matrices, constructed to look somewhat similar to Raven's Advanced Progressive Matrices (Raven et al., 1985). Participants will be randomly informed that they performed these tasks either successfully or poorly (failure condition) upon completion.

Participants will then be required to complete some repeated measures:

- PANAS-X
- RSQ-15

Once the questionnaires and tasks have been completed, the Biolog fetropdes and respiration transducer will be removed from the participant, and they will be offered a Kleenex to clean their skin of any residue left by the fetropdes.

Finally, after a four-week period, participants will be asked to complete some follow-up measures:

- CES-D
- STAI
- PSQI
- PERI

7. Check all research activities that apply. *Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.).*

<input type="checkbox"/> Anesthesia (general or local) or sedation	<input type="checkbox"/> Magnetic Resonance Imaging (MRI)
<input type="checkbox"/> Audio, video, digital, or image recordings	<input checked="" type="checkbox"/> Materials that may be considered sensitive, offensive, threatening, or degrading
<input type="checkbox"/> Biohazards (e.g., rDNA, infectious agents, select agents, toxins)	<input checked="" type="checkbox"/> Non-invasive medical procedures (e.g., EKG, Doppler)
<input type="checkbox"/> Biological sampling (other than blood)	<input type="checkbox"/> Observation of participants (including field notes)
<input type="checkbox"/> Blood drawing, injections, surgical procedures (including biopsies) → Complete <a href="#">Appendix Q</a>	<input type="checkbox"/> Oral history (does not include medical history)
<input type="checkbox"/> Coordinating Center	<input type="checkbox"/> Placebo
<input type="checkbox"/> Data, not publicly available	<input type="checkbox"/> Pregnancy testing
<input type="checkbox"/> Data, publicly available	<input type="checkbox"/> Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) → Complete <a href="#">Appendix V</a>
<input type="checkbox"/> Data/Specimen storage/repository → Complete <a href="#">Appendix C</a> (future unspecified use, including research databases for purposes of sharing data or specimens collected with other researchers/studies in the future)	<input type="checkbox"/> Record review (which may include PHI)
<input checked="" type="checkbox"/> Deception → Complete <a href="#">Appendix D</a> & <a href="#">Appendix M<sub>1</sub></a>	<input type="checkbox"/> Specimen research
<input type="checkbox"/> Devices → Complete <a href="#">Appendix E</a>	<input type="checkbox"/> Stem cell research
<input type="checkbox"/> Diet, exercise, or sleep modifications	<input checked="" type="checkbox"/> Surveys, questionnaires, or interviews (one-on-one)
<input type="checkbox"/> Drugs or biologics → Complete <a href="#">Appendix F</a>	<input type="checkbox"/> Other:
<input type="checkbox"/> Emergency research	Specify: <span style="background-color: #cccccc; display: inline-block; width: 50px; height: 15px;"></span>
<input type="checkbox"/> Focus groups	
<input type="checkbox"/> Food supplements	
<input type="checkbox"/> Gene transfer	
<input type="checkbox"/> Genetic testing → Complete <a href="#">Appendix G</a>	
<input checked="" type="checkbox"/> Internet or e-mail data collection	

8. Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.



Explanation of the study and informed consent, and administration of the physiological measures is expected to take about 10 minutes. The initial set of questionnaires are expected to take a total of about 20-30 minutes to complete, as each measure is relatively brief in length. Participants will be instructed to complete as many anagrams as they can for a total of 5 minutes. The matrices task will be composed of 10 items and participants will be allotted a time of 30 seconds to answer each item, spending a total of 5 minutes on this task. The two tasks will be presented in a counter-balanced order throughout the entire study. The measures following these tasks are expected to take no more than 10 minutes to complete. Therefore, this initial portion of the study is expected to take no more than an hour for participants to finish. For the follow-up portion of the study, after 4 weeks participants will be sent measures to complete electronically. These measures are not expected to take more than 10-15 minutes to complete.

#### Section 4 - PARTICIPANT POPULATION

- a. What is the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Kent State IRB approval:

**80**

*The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.*

- b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).



**The number of participants proposed above was derived from a power analysis (statistical rationale) and with consideration of the likely attrition rate of undergraduate participants, particularly concerning the follow-up portion of the study.**

- c. Specify the age(s) of the individuals who may participate in the research:



Age(s): **18 and older**

d. Specify the participant population(s) to be included (check all that apply):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Adults  | <input type="checkbox"/> Pregnant women/fetuses → Complete <a href="#">Appendix K</a><br>(Only if pregnant women are <i>intentionally</i> recruited and/or studied) |
| <input type="checkbox"/> Adults with decisional impairment → Complete <a href="#">Appendix W</a>  | <input type="checkbox"/> Prisoners → Complete <a href="#">Appendix L</a>  |
| <input type="checkbox"/> Children (< 18 years) → Complete <a href="#">Appendix I</a> .<br>Research involving minors must adhere to <a href="#">University policy 5-19</a> . | <input checked="" type="checkbox"/> Student research pools (e.g., psychology, sociology, communication) → Complete <a href="#">Appendix Y</a>                       |
| <input type="checkbox"/> Neonates (uncertain viability/nonviable) → Complete <a href="#">Appendix K</a>   | <input type="checkbox"/> Unknown (e.g., research using secondary data/specimens, non-targeted surveys)  |
| <input type="checkbox"/> Non-English speaking → Complete <a href="#">Appendix J</a>   | <input type="checkbox"/> Other<br>Specify: <input type="text"/>   |

*The regulations require that, "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects." 45 CFR 46.111(b). There are additional, explicit regulatory requirements regarding pregnant women and fetuses (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C) and children (45 CFR 46 Subpart D and 21 CFR 50 Subpart D). The questions in the applicable appendices address these additional requirements.*

e. Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

**The participants will be undergraduate students recruited through the introductory level psychology courses at Kent State University. As our research question regards performance and perfectionism as a main factor to examine, the use of college students in an academic setting is certainly fitting and appropriate for obtaining information about achievement-related constructs. College student samples are also known to be convenient and typically used for most psychological studies for economical and practical reasons.**

f. Will any participants be **excluded** based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status? ☒ Yes ☐ No

**If Yes** → Explain the criteria and reason(s) for each exclusion. *Consider the study's scientific or scholarly aims and risks.*

**We will be using a convenience sample of undergraduate college students, so children and individuals not affiliated with the university would not be able to participate in the experiment.**

g. Are any of the participants likely to be vulnerable to coercion or undue influence? *Consider students, employees, terminally ill persons, or others who may have limited autonomy.*

*The regulations require that, "An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."*

☐ Yes  
☒ No

**If Yes** → Describe additional safeguards to protect participants' rights and welfare. *Consider strategies to ensure voluntary participation.*

## Section 5 - RISK/BENEFIT ASSESSMENT

a. Do you think that the probability and magnitude of harm or discomfort

☐ Yes

anticipated for the participants are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?

☒ No

**If Yes →** Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

- 
- b. Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. Consider the range of risks, including physical, psychological, social, legal, and economic.

Limited harm or risk is expected to result from the research, however students will be asked to complete questionnaires regarding their mood and personal experiences, as well as instructed to complete tasks under the assumption that their performance is being evaluated – in this vein, some psychological discomfort may possibly result during or at the termination of the study. Also, there is the chance that students may feel slight distress or discomfort from wearing the physiological measures, as they will be aware that their biological responses are being monitored. Participants will be informed prior to the study verbally and in written form of the requirements of the study and their right to not complete any upsetting information in the questionnaires or withdraw from the study at any time, should they desire. It will also be made clear to participants that they will not be penalized should they withdraw. Participants will be debriefed following the conclusion of initial and follow-up portions of the study about the true purpose of each portion of the experiment.

- 
- c. Describe how risks, harms, and/or discomforts will be minimized. *If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders, etc.), address timing and method of testing; include how positive test results will be handled.*

As mentioned above, immediate minimization of potential risks, harm, or discomfort to participants will entail providing information to participants prior to the study in the form of verbal and written informed consent, and at the conclusion of the study in the form of proper debriefing. If any participants seem or report feeling upset or disturbed by the proceedings of the study, research assistants will report this to the principle investigator and/or key investigator who will follow-up with the participant. Participants will be reminded of the possibility of making an appointment with the Kent State Psychological Clinic in the event that there are any severe emotional concerns that need to be addressed or discussed. We will provide all participants directions to and information for the Kent State Psychological Clinic for them to contact if any issues arise. Lastly, a list of local psychological resources will be provided in the event that a participant feels extreme emotional upset after completing the study.

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- d. List the potential benefits that individual participants, society or both may expect as a result of this research study. State if there are no direct benefits to individual participants. *Compensation is not to be considered a benefit.*

**While there are no direct or immediate benefits to participants, indirect benefits of this research study**

include further understanding of the construct of perfectionism and the mechanisms by which it is connected to negative changes in affect and mood, and by which this maladaptive relationship may be controlled or prevented during times of duress for vulnerable persons. Considering much of the adult population is regularly placed in situations of an evaluative nature where performance is strongly valued (i.e., school, work, relationships, etc.), the research could provide support for the development of more effective methods or techniques to reduce everyday stress or psychological discomfort in students as well as other working adults.

- e. Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

Limited or minimal risk is expected to result from participation in this study, so it can be stated that the anticipated benefits will outweigh any potential risks. The initial portion of the study is relatively brief and any possible risks or upsets (changes in affect) resulting from participation are expecting to be correspondingly transient. The secondary portion of the study will only require participants to complete several questionnaires electronically – this session is not expected to take much of the participant's time, and if any participant should experience duress or discomfort from completing either session, they will have been informed of their option to withdraw from the study if they desire, and also provided with relevant information on how to access the Kent State Psychological Clinic or other outside psychological resources. As mentioned above, the benefits to the research are indirect but yet have importance in that further information may be obtained regarding the relationship between performance-based concerns (perfectionism, rumination) and subsequent distress, and ways to alleviate or prevent such effects of the relationship.

- f. Is it possible that this study will discover a previously unknown condition such as a disease, suicidal intentions or genetic predisposition in a participant as a result of the study procedures?

☐ Yes  
☒ No

If Yes → Explain how you will manage the situation.

- g. Will this study collect information about research participants' family history that includes personal identifiers (e.g., secondary subjects)?


☐ Yes → Complete [Appendix P](#)  
☒ No

- h. Is this a double blind randomized study in which neither the participants nor the research team knows the assignment to the study drug or placebo?

☐ Yes  
☒ No

If Yes → Describe the unblinding plan

## Section 6 - PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

a. Specify the recruitment methods for this study and attach a copy of recruitment material(s): 

- |   |  |
|---|--|
| <input type="checkbox"/> Personal contact<br><input type="checkbox"/> Contact or approach letters<br><input type="checkbox"/> Telephone calls (include script)<br><input type="checkbox"/> Brochures<br><br><input type="checkbox"/> Printed advertisements | <input type="checkbox"/> Flyers<br><input checked="" type="checkbox"/> Internet<br><input type="checkbox"/> Home visits<br><input type="checkbox"/> Radio or TV (include written text of the advertisement and brief layout of images)<br><input checked="" type="checkbox"/> Email (include copy of text to be used)<br>Specify frequency: <b>Participants will be sent weekly e-mails (a total of three, following the first week concluding the first portion of the study) regarding the follow-up portion of the study, to occur four (4) weeks later.</b><br><br><input type="checkbox"/> Other<br>Specify: <span style="background-color: #cccccc; display: inline-block; width: 50px; height: 15px;"></span> |
|---|--|

Who will approach or recruit potential participants?

- ☐ Principal Investigator and/or Co-Investigator  
☒ Research Staff  
☐ Other → **please describe:**

b. When/how often will participants be recruited? (e.g., before/after a counseling visit, via email with 3 reminders sent at specific intervals)

**Participants will be initially recruited only once through the online university research participant pool website. Recruitment will begin at the start of the Fall 2015 semester. With regard to the follow-up portion of the study, participants will be sent weekly reminder e-mails up until their scheduled participation. Follow-up is expected to be 4 weeks after completion of the initial portion of the study, so a total of 3 reminder e-mails will be sent.**

c. Where will participants be recruited? (e.g., doctor's office, classroom, online)

**Participants will be recruited online through the university undergraduate research participant pool system.**

d. What steps will be taken to avoid coercion or undue influence in the *recruitment* of research participants? (e.g., will the potential participants be afforded the opportunity to take material home and discuss the study with family members and/or primary care providers?)

**General information regarding the study will be provided to any interested persons through the university's electronic research participant pool system to prevent any coercion or undue influence. Participants will have as much time as needed to determine if they are interested in learning more information or even participating in the study. If participants choose to sign-up for the study, they will be verbally given more details about the study upon arrival to the laboratory, prior to signing informed consent which will include statements that their participation is completely voluntary, that they have the option to withdraw from the study at any time, and that their consent and any completed measures or tasks will be voided from the study should they choose to do so. If participants decline signing consent and participating in the study, or should they choose to withdraw from the proceedings of the study, they will not be penalized and will be informed of this as well.**

## Section 7 - INCENTIVES or COMPENSATION TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? ☒ Yes

Compensation plans should be pro-rated (not contingent upon study completion) and should consider participation withdrawals, as applicable.

☐ No

If Yes → Describe the compensation/incentive. Include the amount and timing of all payments.

Participants will be allotted course credits for their participation in the initial portion of the study. As this portion of the study is expected to take no more than an hour, participants will be able to earn up to 2 points. Participants will also be informed that in exchange for their full participation in the study, they will be included in a raffle for the opportunity to win a prize valuing \$50, for every 10 participants that register for and complete the study. After 10 participants complete the study, the randomly chosen participant shall be notified they have won and will receive their prize once all data has been collected and the research study has ended. Participants will also be informed that select winners of the prize(s) shall still be compensated for their participation, even if the desired number of subjects do not complete the study (for instance, if only 39 participants are obtained at the conclusion of the study, 4 prizes will be distributed, and so forth). All prizes will be distributed at the conclusion of the follow-up portion of the study.

- a. Have you reviewed and complied with the *Procedures for Compensating Research Participants* policy that is available on our website at <http://www.kent.edu/research/researchsafetyandcompliance/irb/forms.cfm>? ☒ Yes ☐ No



## Section 8 - INFORMED CONSENT PROCESS

The human subject protection regulations at 45 CFR 46:

- List ten basic elements of information that must be provided to subjects when investigators are seeking informed consent from subjects to participate in research (unless the IRB approves a request for a waiver/alteration of any/all of the basic elements for consent.) The basic elements of consent are:
  - ✓ Purpose, procedures and expected duration of the research
  - ✓ Risks and discomforts
  - ✓ Potential benefits
  - ✓ Alternative procedures or treatments (if any)
  - ✓ Compensation for participation in the research (if any)
  - ✓ Provisions for confidentiality
  - ✓ Management of research related injury
  - ✓ Contacts for additional information
  - ✓ Voluntary participation and the right to discontinue participation without penalty
- Require that participants sign a consent form (unless the IRB approves a request for a waiver of documented consent.)

If participants cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under 18) or when they are mentally incapacitated, consent from a legal representative (such as a parent or legal guardian) is required.

To develop a consent form, begin by using the consent form template that is available from our website at

- a. Who will discuss and obtain consent from participants? ☐ Principal Investigator ☒ Research key personnel ☐ Other: Specify
- b. Are you requesting approval for a waiver/alteration of any/all of the basic elements of consent (see information above) for any part of the research? ☒ Yes → Complete [Appendix M1](#)  ☐ No  
(e.g., investigators conducting research that involves deception might request a waiver/alteration of the basic elements of consent so that the true purpose of the research is not disclosed in the consent form.)
- c. Are you requesting a waiver of the requirement for participants to sign a consent document? ☐ Yes → Complete [Appendix M2](#)  ☒ No  
(e.g., an investigator conducting research that only involves the use of anonymous surveys might request a waiver of signed consent.)

- d. Describe who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)? ☐ N/A


**Participants are expected to be aged 18 and older, so they will complete the informed consent forms.**

- e. Check all that apply:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Informed Consent– Signed Form → <b>Provide copies of document. Please use website template</b> | <input type="checkbox"/> Parental Permission – Form   |
| <input type="checkbox"/> Informed Consent – Verbal Script/Online/Unsigned form → <b>Provide copies of script/document.</b>         | <input type="checkbox"/> Parental Permission – Verbal Script/Online/Unsigned  |
| <input type="checkbox"/> Assent – Form   | <input type="checkbox"/> Translated Consent/Assent – Form(s), Script(s), etc. (provide copy of English version with description the qualifications of the translator. |
| <input type="checkbox"/> Assent – Verbal/Online/Unsigned   | <input type="checkbox"/> Photograph/video/audio taping consent form (or permission for photographs/video/audiotaping included as section on informed consent)         |
| <input type="checkbox"/> Not Applicable (existing data or specimens)   | <input type="checkbox"/> Other (Specify):   |



- f. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.

**Information regarding the study and how to participate in the study will be available through the university's online research participant pool system. Once subjects have scheduled a time to attend the study and arrive at the study location, they will again be provided more information about the study regarding estimated length and procedures and provided the opportunity to ask any relevant questions. Participants will then be given a written informed consent form and told that their participation is completely voluntary and that they may withdraw from the experiment at any time should they choose to, without fear of penalization. Subjects will begin the experiment immediately after agreeing to and signing the consent form.**

- g. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension? ☐ Yes → **Provide copies of these tools**   
☒ No

## Section 9 - HIPAA RESEARCH AUTHORIZATION

- a. Will individually identifiable Protected Health Information (PHI) subject to the [HIPAA Privacy Rule](#) requirements be accessed, used, or disclosed in the research study?

- ☒ No
- ☐ Yes → **Check all that apply:**
- ☐ Written Authorization → **Provide a copy of the Authorization Form**
  - ☐ Partial Waiver of authorization (recruitment purposes only; preparatory to research) → Complete **Appendix N** 
  - ☐ Full Waiver of authorization (limited data set with no direct identifiers and with a data use agreement; information on descendant's) → Complete **Appendix N** 

## Section 10 - PRIVACY OF PARTICIPANTS

- a. Describe the provisions to protect the privacy interests of the participants. *Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.*

In order to protect the privacy of participants, all data collection forms will be stored in the [REDACTED]. Forms will be stored behind locked doors and in a locked filing cabinet pending data entry. Participant names and identifying information will be stored separately from the data, linked only by subject number. The consent forms will be the only link between participant names and numbers, and these will be stored in a locked file cabinet in the [REDACTED] as well. Data entry will occur in the [REDACTED] at Kent State University, and only project personnel will have access to the data. All research personnel will be trained to follow proper data safety procedures and to maintain strict confidentiality.

- b. Does the research require access to personally identifiable private information?

☐ Yes

☒ No

**If Yes →** Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

[REDACTED]

- c. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality. ☐ N/A

None of our questions will ask about harm to self or others, physical or sexual abuse, however in the event that problems arise with regards to these issues, appropriate action will be taken in accordance with The Ohio Revised Code as well as the American Psychological Association's Ethical Code. This includes breaking confidentiality and communicating any safety concerns.

- d. Will this study obtain IDENTIFIABLE information from students' *educational* records?

☐ Yes

☒ No

**If Yes →** Does the individual obtaining the information have legitimate access (e.g. as the student's teacher/professor)?

☐ Yes

☐ No

*The FERPA (Family Educational Rights and Privacy Act) applies when student educational records are used for research. FERPA requires a signed permission when IDENTIFIABLE information from student records is released to anyone who did NOT already have legitimate access.*

## Section 11 - CONFIDENTIALITY OF DATA

- a. What format will be used to store participant information? Check all that apply.

☒ Hardcopy paper documentation

☐ Audio Tapes

☒ Database system

☐ Video Tapes

☐ Disk (CD ROM, floppy disk, flash drive)

☐ Other

Specify: [REDACTED]



b. How will the participant information be kept secure and confidential? Check all that apply.

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> File cabinets with combination or key lock<br><br><input checked="" type="checkbox"/> Locked room with cardkey access<br><br><input type="checkbox"/> Off-site backup vendor<br><br><input checked="" type="checkbox"/> Electronic records with user identification/password | <input type="checkbox"/> Biometric authentication (e.g. fingerprints, voice, retinal/iris scan)<br><br><input type="checkbox"/> Freezer with a padlock<br><br><input type="checkbox"/> NIH Certificate of Confidentiality<br><br><input type="checkbox"/> Other<br>Specify: <span style="background-color: #cccccc; padding: 0 20px;"> </span> |
|--|--|

c. Will you be retaining identifying information for purposes of another research project (e.g. keeping participants' contact information to recruit them for future research)?

- ☐ Yes  
☒ No

**If Yes →** Describe what information will be retained. The information must also be described in the consent form.

d. How will access to participant information be revoked when a staff member leaves the study?

**The staff member will not have access to the key to the locked filing cabinet. With regard to cardkey access, their cardkey will be collected upon completion of work with the study. Their ability to access data entry computers, including computer log-ins and passwords, will also be deactivated.**

e. Will you be sharing or receiving research data for this project with/from researchers outside of Kent State University?

- ☐ Yes  
☒ No

**If Yes →** provide copy of Data Use Agreement, if applicable.

f. Will you be sharing or receiving materials or specimens for the purposes of this project with/from researchers outside of Kent State University?

- ☐ Yes  
☒ No

**If Yes →** complete a [Materials Transfer Agreement](#) 

g. Indicate what will happen to the identifiable data at the end of the study. *Research data should be retained for a minimum of three years after final project closeout (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)*

- ☐ Identifiers will be permanently removed from the data and destroyed (de-identified)  
☒ Identifiable/coded (linked) data will be retained and stored confidentially  
☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)  
☐ Identifiable data were not collected

## Section 12 – COST TO PARTICIPANTS or REIMBURSEMENTS

a. Are there any potential costs that participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

- ☐ Yes  
☒ No

**If Yes →**  

b. Are there any costs to participants that will be covered/reimbursed by the research study.

- ☐ Yes  
☒ No

**If Yes →**

### Section 13 - ASSURANCE: PRINCIPAL INVESTIGATOR

I agree to follow all applicable policies and procedures of Kent State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Perform the research as approved by the IRB with appropriately trained and qualified personnel with adequate resources;
- Initiate the research only after written notification of IRB approval has been received;
- Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others;
- Provide significant new findings that may relate to the subjects willingness to continue to participate;
- Inform the IRB of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the KSU IRB (except where necessary to eliminate apparent immediate hazards to participants);
- Complete and submit a Continuing Review of Human Subjects Research application before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities;
- Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- Contact the Research Compliance for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g., sabbatical or extended leave);
- Provide a Final Study Report to the IRB when all research activities have ended (including data analysis with individually identifiable or coded private information); and
- Inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

I verify that the information provided in this Use of Human Subjects in Research application is accurate and complete.

---

Signature of Principal Investigator



---

Date



## **Informed Consent to Participate in a Research Study**

**Study Title:** [REDACTED]

**Principal Investigator:** [REDACTED]

You are being invited to participate in a research study. This consent form will provide you with information on the research project, what you will need to do, and the associated risks and benefits of the research. Your participation is voluntary. Please read this form carefully. It is important that you ask questions and fully understand the research in order to make an informed decision. You will receive a copy of this document to take with you.

### **Purpose:**

The current study will be examining how some cognitive abilities and processes may be associated with our mood and emotions. Research has indicated some association between positive mood and increased recall of information, information processing, creativity, and confidence in providing correct responses during testing. Some cognitive decline in fluid intelligence has been associated with elderly depressed and anxious populations, however there is less research on aspects of cognitive processing, such as processing speed, mental flexibility, and visuospatial ability and mood or distress in younger adults. We endeavor to examine if certain cognitive processes related to intelligence or achievement correspond to particular mood states in college students.

### **Procedures**

If you decide to participate, you will be asked to complete the following phases of the study: First, we will attach electrodes to your forearm, collarbone, and rib bone to record heartbeats on an electrocardiogram machine. We will also record your respiration by placing a device similar to a strap around your ribcage. Next you will be asked to fill out some questionnaires about your feelings and personal attributes. Following this, you will be directed to complete some cognitive tasks, similar to those completed for intelligence testing. These tasks will be brief and should take around ten minutes to complete. Then, you will be asked to complete some additional questionnaires regarding your feelings at that time. You will also be provided the opportunity to receive feedback and ask any questions you may have regarding the tasks. This portion of the study is expected to take no more than 45 minutes to complete.

Lastly, you will be contacted by e-mail and sent questionnaires to complete approximately four weeks after completing the initial portion of the study. These questionnaires will ask about your feelings and personal experiences since completing the first portion of the study. The electronic questionnaires would be expected to take no more than 10 minutes to complete.

### **Benefits**

[REDACTED]



This research will not benefit you directly. However, your participation in this study will help us better understand potential relationships between the ways in which we process information and our moods and emotions. If an association is found between cognitive abilities and mood, future studies may examine how strengths in certain forms of information processing may be utilized to promote adaptive emotions. We expect that efficient and advanced information processing during completion of cognitive tasks will be related to stable or improved mood.

### **Risks and Discomforts**

A potential risk that can result from the study is discomfort answering questions about mood and personal attributes. It is not expected that the items or information will contribute to worsening of thoughts or mood, but if you should experience discomfort or do not wish to answer certain items, you may skip them and progress through the questions in the questionnaire. If you have concerns or questions regarding the cognitive tasks, you will have the opportunity to discuss them at the end of the study. If you begin to experience discomfort and would like to withdraw from the study, you may do so at any time without any form of penalization. The examiner and/or research staff may also refer you to the Kent State Psychological University Clinic downstairs (tel: (330) 672-2373) or other related services if needed.

### **Privacy and Confidentiality**

To address the possibility of a breach of confidentiality, numbers will be assigned to all study participants; only these numbers will be directly tied to study data. Linkage between subject numbers and names will only be possible for study staff for purposes of follow-up and compensation, and even then, all records of such name and number links will be permanently destroyed upon completion of data collection. All forms pertaining to this research will be stored behind locked doors and in locked in a filing cabinet in the research lab pending data analysis. Any identifying information that is collected will be stored separately from the data. The consent forms will be the only link between names and numbers, and this information will be stored in a locked file cabinet as well.

### **Compensation**

Participants who complete the study will be provided points or credits for their respective courses; as the study is not expected to take more than an hour to complete, this means you will be able to earn up to two (2) points for the initial portion of the study. Those who choose to participate in the study will also have the potential for compensation in the form of a gift certificate or an item of equal value worth \$50 at its conclusion. For every ten (10) participants that enter and complete the study, including the follow-up portion, one randomly chosen participant will be awarded the gift certificate or item, similar to the process of a raffle drawing. In the event that a full factor of ten (10) does not participate in the study, a winner will still be chosen and rewarded. For instance, if 29 participants complete the study, three (3) persons will receive gifts.

### **Voluntary Participation**

Taking part in this research study is entirely up to you. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise



entitled. You will be informed of any new, relevant information that may affect your health, welfare, or willingness to continue your study participation. Whether you choose to participate or withdraw from the study, the decision will not affect your course grade.

### **Contact Information**

If you have any questions or concerns about this research, you may contact Jeffrey Ciesla, Ph.D. at (330) 672-1182. This project has been approved by the Kent State University Institutional Review Board. If you have any questions about your rights as a research participant or complaints about the research, you may call the IRB at 330.672.2704.

### **Consent Statement and Signature**

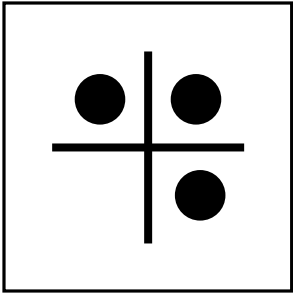
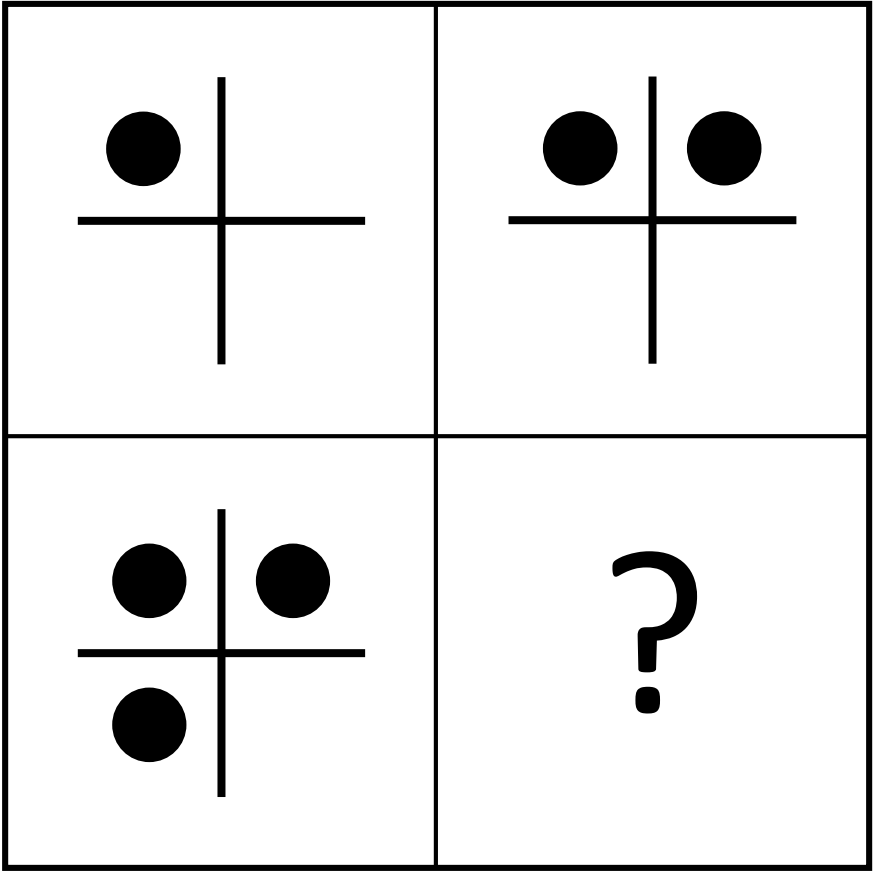
I have read this consent form and have had the opportunity to have my questions answered to my satisfaction. I voluntarily agree to participate in this study. I understand that a copy of this consent will be provided to me for future reference.

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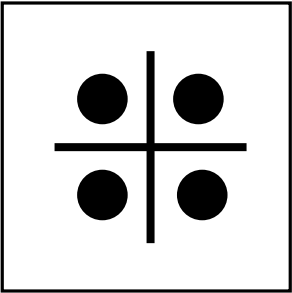
**Participant Signature**

---

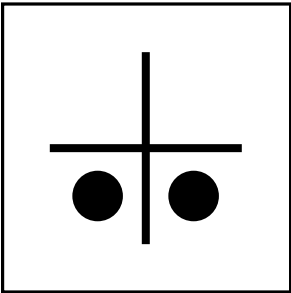
**Date**



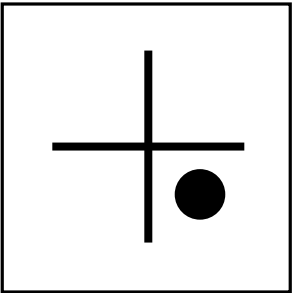
A



B



C



D



### Waiver or Alteration of Consent Process

**INSTRUCTIONS for INVESTIGATORS:**

1. Complete this form to request a waiver or alteration of the consent process. DHHS regulations permit waivers (or alterations) of the consent process if the research meets certain conditions; however, FDA has no provision for waiver or alteration of consent.
2. Do not complete this form to request a waiver of documentation (a signature) of consent, use [Appendix M2](#).
3. Submit this completed document with the Human Subjects Research application via email attachment. To submit the form with a typed signature, the form must be submitted from the Investigator's @kent.edu email account. If completed form is signed and then scanned as a PDF attachment, the @kent.edu email requirement does not apply.

Do NOT begin data collection prior to receiving notification from the KSU IRB that the research has been fully approved.

IRB LOG #:

IRB Office use only

AGENDA DATE

Date received

**To complete this form: Single left-click to complete text fields. To check a box, double left-click on the box, then click "checked". Click OK.**

### Section I - KSU Investigator Information

Last Name: Ciesla      First Name: Jeffrey

Title of Study (should match Human Subjects Research Application)

#### ***Perfectionism, Mindfulness, and Negative Affect & Mood***

1. Indicate the type of waiver/alteration requested:

- ☐ Waiver of Consent Process (e.g., collection or study of existing data, documents or records or research that solely involves program evaluation)
- ☒ Alteration of Consent Process (e.g., research that involves deception may require an alteration of the consent process so that that true purpose of the research is not disclosed. Also in research where the use of implied consent is used, for example via the return of an anonymous survey typically requires an alteration of the consent process)

2. Is the research subject to FDA regulations (i.e., involves use of a food, drug, biologic, device)? ☐ Yes

*If the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application, consent cannot be waived.* ☒ No

3. Is the research (or demonstration project) subject to the approval of state or local government officials and designed to study public benefit or service programs or procedures for obtaining benefits under those programs, changes in or alternatives to those programs or procedures, or changes in methods or levels of payment for benefits or services under those programs? ☐ Yes
- ☒ No

**If Yes →** explain why the research could not 'practicably' be carried out without the waiver or alteration.

*Inconvenience or expense is not an adequate response, as it does not satisfy the criterion for waiver or alteration.*







IF NO questions #2 and #3 → complete #4-7 below to request waiver or alteration.

4. Explain how the research involves no more than minimal risk.

Limited or minimal risk is expected to result from participation in this study, as the initial portion of the study is relatively brief and any possible risks or upsets (changes in affect) resulting from participation are expecting to be correspondingly transient. The secondary portion of the study will only require participants to complete several questionnaires electronically – this session is not expected to take much of the participant's time, and if any participant should experience duress or discomfort from completing either session, they will have been informed of their option to withdraw from the study if they desire, and also provided with relevant information on how to access the Kent State Psychological Clinic or other outside psychological resources.

5. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

Participants will be informed that they can withdraw from the study at any time and withdraw their data from being included in the analysis, without threat of penalty, and also provided the opportunity to ask questions and comment on their reaction to the study once they have been debriefed of the true nature of the study. Participants will not be coerced in any way to join or take part in the study, and any alterations to the nature of the study will be revealed immediately upon the participants' completion.

6. Explain why the research could not 'practicably' be carried out without the waiver or alteration.

*Inconvenience or expense is not an adequate response, as it does not satisfy the criterion for waiver or alteration.*

Although participants will be provided a written informed consent form to complete, if the form detailed the true purpose of the study, such information could affect participants' responses to study measures and their performance in the manipulation tasks. Without the alteration to the form, participation in the study could jeopardize proper interpretation and reporting of any data collected from the study.

7. Will the participants be provided with additional pertinent information after participation?

☒ Yes

☐ No

Explain why or why not:

Appropriate debriefing will be provided at the conclusion of portions of the study and information will be offered regarding the Kent Psychologic Clinic and other resources, should participants experience any potential duress or upset, and to prevent any risks or harm, resulting from events in the study.



### Research that involves DECEPTION

#### **INSTRUCTIONS for INVESTIGATORS:**

1. Complete this form to request the use of deception in the proposed research. **Be sure to:**
  - Complete and attach **Appendix M1** to request a waiver or alteration of the consent process because when research involves deception, participants are not fully informed about the research when they consent to participate.
  - Attach the debriefing script or information sheet to be used to explain the research to the participants.
2. Submit this completed document with the Human Subjects Research application via email attachment. To submit the form with a typed signature, the form must be submitted from the Investigator's @kent.edu email account. If completed form is hand-signed and then scanned as a PDF attachment, the @kent.edu email requirement does not apply.
3. Do NOT begin data collection prior to receiving notification from the KSU IRB that the IAA agreement has been fully approved.

#### **DEFINITIONS**

##### ***Deception:***

*A procedure in which investigators deliberately mislead participants during research by withholding information or providing false information. As a result, participants are not fully informed about the research when they consent to participate.*

IRB LOG #:

IRB Office use only

AGENDA DATE

Date received

Date of IRB Determination  
email to Investigator

***To complete this form: Single left-click to complete text fields. To check a box, double left-click on the box, then click "checked". Click OK.***

#### **Section I - KSU Investigator Information**

Last Name: **Ciesla**      First Name: **Jeffrey**

Title of Study (should match Human Subjects Research Application)

##### ***Perfectionism, Mindfulness, and Negative Affect & Mood***

1. Describe which aspects of the research procedures will be withheld from the participants.

**The participants will not be informed of the true purposes of the study in the informed consent, as such knowledge would potentially affect participation and performance in the study.**

2. Provide the scientific rationale for deceiving the participants.

**The study is examining measures of perfectionism, which would require a willingness to complete tasks, and also response to failure or success conditions. If informed of the true purpose of the study, the results and any interpretation of data could be affected by effortless performance or social desirability on the part of the participants.**

3. Describe how and when the participants will be told the true purpose of the research and the reason for the



---

deception.

Participants will be told at the conclusion of each portion of the study (initial and follow-up) about the purposes of the research and reasoning for deception. At the conclusion of the initial portion of the study, participants will be informed that they were being evaluated on their persistence in completing the tasks and their response to success or failure conditions in relation to mood. At the conclusion of the follow-up portion of the study, participants will be informed that the main aim of the study was to evaluate types of perfectionism, ability to be mindful, and potential relationships to affect or mood.

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4. State who will inform the participants about the deception.

**Key Personnel will inform the participants about the deception concluding participation in the study.**

---

5. Explain opportunities (if any) for participants to discuss their responses to the deception and/or to withdraw the use of their data from the research once that they find out that they have been deceived.

Participants will be provided the opportunity to ask any questions or express concerns about the tasks or the deception at the conclusion of the initial portion of the study. If they wish to withdraw the use of their data, they will be informed of this option as well. Participants will similarly be informed and given the opportunity to contact the researcher at the conclusion of the follow-up questionnaires, should they have any questions or concerns about the study.

## APPENDIX A1 – Co-Investigator(s) or Key Personnel



### KSU Co-Investigator(s) or Key Personnel

<p><b>INSTRUCTIONS for INVESTIGATORS:</b></p> <ol style="list-style-type: none"> <li>1. Complete this form to add <u>KSU-affiliated</u> Co-Investigator's or Key Personnel to research that involves human subjects.</li> <li>2. Submit this completed document with your application via email attachment. To submit the form with a typed signature, the form <u>must be</u> submitted from the Investigator's @kent.edu email account. If completed form is signed and then scanned as a PDF attachment, the @kent.edu email requirement does not apply.</li> <li>3. Do NOT begin data collection prior to receiving notification from the KSU IRB that the study/modification has been fully approved.</li> </ol> <p><b>DEFINITIONS</b></p> <p><b>Key personnel:</b>  <i>Individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.</i></p> <p><i>Conflict of Interest is a financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family that may exert a substantial and improper influence on the individual's professional judgment in exercising any institutional duty or responsibility, including the conduct or design of research.</i></p> <p><b>Financial Conflict of Interest:</b>  <i>An interest of an individual (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research or an individual's interest in any entity whose financial interests would reasonably appear to be affected by the research. Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).</i></p> <p><b>Non-Financial Conflict of Interest:</b>  <i>An interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with the obligation to protect research participants and potentially compromises the objectivity and credibility of the research process.</i></p> <p><b>Immediate Family:</b>  <i>An Investigator's or Key personnel's spouse or domestic partner and dependent children.</i></p>	<p>IRB LOG #:</p> <p><b>IRB Office use only</b></p> <table border="1"> <tr> <td>AGENDA DATE</td> <td></td> </tr> <tr> <td>Date received</td> <td></td> </tr> <tr> <td>Date of IRB Determination email to Investigator</td> <td></td> </tr> </table>	AGENDA DATE		Date received		Date of IRB Determination email to Investigator	
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**To complete this form: Single left-click to complete text fields. To check a box, double left-click on the box, then click "checked". Click OK.**

### Section I - KSU PRINCIPAL INVESTIGATOR INFORMATION

Last Name:  First Name:

Title or, IRB log number of Research (should match Human Subjects Research Application)



KSU Co-Investigator(s) or Key Personnel

**KSU CO-INVESTIGATOR(S) and/or KEY PERSONNEL (#1)**

- ☐ Co-Investigator      Status:
- ☒ Key Personnel      ☐ Faculty ☒ Graduate Student ☐ Undergraduate Student ☐ Staff

Name (Last, First, MI): [REDACTED]

E-mail: [REDACTED]@kent.edu

Phone: [REDACTED]

- a. Have Co-Investigator(s)/Key personnel completed the CITI online (or equivalent) training? ☒ Yes → attach copy of completion certificate. ☐ No
- b. Describe the role/activities that this Co-investigator or Key Personnel will perform for this study (e.g., subject recruitment, informed consent):

**Key personnel will be involved in most of the roles of the study including subject recruitment, data collection and analysis, and debriefing of participants. Research staff will be trained to provide informed consent and the questionnaires and tasks to participants, to ensure that the experimenter or key personnel is blind to the experimental groups. Key personnel will track all of the data forms and ensure that participants are fully debriefed at the conclusion of the study. Key personnel will also ensure that participants receive appropriate compensation for their part in the study.**

- c. Where will the Co -investigator or Key Personnel perform the research activities? ☒ at KSU ☐ at external research site → complete Appendix O
- d. Does Co-Investigator or Key personnel have a Conflict of Interest related to the research? ☐ Yes → provide explanation below ☒ No

Explanation:

- e. Does Co-Investigator or Key personnel have a patent or, pending patent, or current patent idea that could be conceivably related to this research project? ☐ Yes → provide explanation below. ☒ No

Explanation:

- f. Has/will Co-Investigator or Key personnel receive funds or, other resources (including equipment, devices, etc...) from a Sponsor or funding agency/entity for purposes of this research project? ☐ Yes → provide explanation below. ☒ No

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Explanation:

I agree to follow all applicable policies and procedures of Kent State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Perform the research as approved by the IRB under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
- Initiate the research after written notification of IRB approval has been received;
- Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others;
- Provide significant new findings that may relate to the subjects willingness to continue to participate;
- Inform the IRB of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the KSU IRB (except where necessary to eliminate apparent immediate hazards to participants);
- If applicable, complete and submit a Continuing Review of Human Subjects Research application before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities;
- Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;

I verify that the information provided in this form is accurate and complete.

Signature \_\_\_\_\_

Date \_\_\_\_\_



## Debriefing Form for Participation in a Research Study Kent State University

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Thank you for your participation in our study! Your participation is greatly appreciated.

### Purpose of the Study:

Earlier in our consent form we informed you that the purpose of the study was to examine how cognitive abilities related to intelligence correspond to mood states in adults. In actuality, our study is about how perfectionism may contribute to mood and psychological distress in response to performance feedback. The tasks you were instructed to complete to gauge your relative intelligence were not valid measures, but created by research staff in order to manipulate the condition such that participants would be motivated to provide maximal effort towards their performance. Thus, whether you were told your performance was 'above' or 'below' average, your actual level of intelligence was not evaluated during any events taking place in the study. Your responses to the completed questionnaires will be retained as a part of the data that will be analyzed for the study, however your responses to the tasks will not.

Unfortunately, in order to properly test our hypothesis, we could not provide you with all of these details prior to your participation. This ensures that your reactions in this study were spontaneous and not influenced by prior knowledge about the purpose of the study. Once again, as the two tasks we required you to complete are not valid measures, your responses to the items were not indicative at all of your intelligence and will not be kept for any future research purposes. If we had told you the actual purposes of our study, your ability to genuinely complete the tasks could have been affected. We regret the deception but we hope you understand the reason for it.

### Confidentiality:

Please note that although the purpose of this study has changed from the originally stated purpose, everything else on the consent form is correct. This includes the ways in which we will keep your data confidential. Identification numbers will be assigned to all study participants; only these numbers will be directly tied to study data. Linkage between subject numbers and names will only be possible for study staff for purposes of follow-up and compensation, and even then, all records of such name and number links will be permanently destroyed upon completion of data collection. All forms pertaining to this research will be stored behind locked doors and in locked in a filing cabinet in the research lab pending data analysis. Any identifying information that is collected will be stored separately from the data. The consent forms will be the only link between names and numbers, and this information will be stored in a locked file cabinet as well.

Now that you know the true purpose of our study and are fully informed, you may decide that you do not want your data used in this research. If you would like your data removed from the





study and permanently deleted, you may indicate this to the research staff and your data will be withdrawn from the study, without any penalty or consequence to you or other participants.

If Applicable: Whether you agree or do not agree to have your data used for this study, you will still receive course credit(s) and be entered in a raffle for the chance to win a reward valued at \$50 for your participation.

If Applicable: Please do not disclose research procedures and/or hypotheses to anyone who might participate in this study in the future as this could affect the results of the study.

#### Final Report:

If you would like to receive a copy of the final report of this study (or a summary of the findings) when it is completed, please feel free to contact us.

#### Useful Contact Information:

If you have any questions or concerns regarding this study, its purpose or procedures, or if you have a research-related problem, please feel free to contact [REDACTED]. If you have other concerns about this study or would like to speak with someone not directly involved in the research study, you may contact the [REDACTED].

This project has been approved by the Kent State University Institutional Review Board (IRB). If you have any questions concerning your rights as a research subject, you may contact the IRB at (330) 672-2704.

If you feel upset after having completed the study or find that some questions or aspects of the study triggered distress, talking with a qualified clinician may help. If you feel you would like assistance please contact the Kent State Psychological Clinic within the department at (330) 672-2372 or the University Health Services Psychological Service Center at (330) 672-2487. In the case of an emergency, please call 911.

#### Further Reading(s):

If you would like to learn more about perfectionism as a potential contributor to psychological distress please see the following references:

- Blatt, S. (1995). The destructiveness of perfectionism: Implications for the treatment of depression. *American Psychologist*, 50, 1003–1020. doi:10.1037/0003-066X.50.12.1003
- Hewitt, P. L., & Flett, G. L. (1991b). Perfectionism in the self and social contexts: Conceptualization, assessment, and association with psychopathology. *Journal of Personality and Social Psychology*, 60, 456– 470.