Surveys and educational tests can only be approved as exempt through self-determination under certain conditions. This decision tree will walk you through the conditions that must be met to obtain approval. You cannot use this sheet to exempt your project. To obtain an exemption through the self-determination process you must complete the online program.

Are you receiving federal funds to support the research?

No

Are you performing a manipulation of the subject or the subject's environment for the purpose of changing their behavior(s), processes, or other endpoint(s)?

No

Does the target population include children (under the age of 18), pregnant women, adults who may not be legally/mentally/cognitively competent to provide consent, or prisoners?

No

Do research procedures include access to, or the collection of Protected Health Information (HIPAA compliance) or Student Educational Records (FERPA compliance)?

No

The information is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects AND Any disclosure of the subject's responses outside of the research could reasonably place the subject at risk of criminal or civil liability or could be damaging to the subject’s financial standing, employability, or reputation.

No

Will the research expose participants to discomfort or distress beyond that normally encountered in everyday life?

No

Does the research involve the use of deception?

No

Does a study team member have a conflict of interest?

No

Complete the online program to obtain a self-determination

Your project is not eligible for self-determination. You must complete either a level I or level II/III form.
Self Determination Survey/Educational Testing Exemption

Start of Block: Default Question Block
Q1 Self Determination - Survey/Educational Testing Exemption

In an effort to decrease faculty workload and phase in revised federal regulations for human subjects research, the IRB is pilot testing an exemption self-determination program. A project can only be approved as exempt through this program under certain conditions. This form is designed to screen for these conditions.

You must complete this form in its entirety to obtain a determination email. The email will be sent to the email address attached to the Flashline user ID that you used to log in.

You may be contacted by the Office of Research Compliance to provide input on the process or for quality assurance purposes.

Information on Survey/Educational Testing Exemption:

Research involving survey and educational testing (cognitive, diagnostic, aptitude, achievement) procedures can be exempt under the federal regulations unless they meet both of the following conditions.

i. the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND

ii. any disclosure of the humans subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

In addition, the IRB has determined that in order to obtain exemption through self-determination other conditions apply. This form is designed to screen studies based on these conditions. If your project is exempted through this program, you will receive an email letting you know that you may begin immediately. If your project is not approved through this program, you will receive an email with instructions on your next steps.

Information on research involving students (the entire policy is available at (copy and paste the link into your browser): https://www.kent.edu/research/office-research-compliance/irb-help):

- De-identification of records must be done to the standards of FERPA laws.
- If students are to be compensated with class credit, an alternative assignment that is of equal effort and credit MUST be offered and described in the consent form.
- The voluntary nature of participation must be emphasized.
- Students should be informed that non-participation will not affect their grades/class standing.
- Investigators wishing to target the enrollment of their own students:
  - must have a valid scientific reason.
  - recruitment should be conducted by a third party.
it is recommended that data be collected by a third party.

Other important information:
You are required to upload the study consent form as part of the self determination process.

Your research procedures must include a recruitment method that informs potential participants that you are conducting research on behalf of Kent State University and provides a basic overview of the research.

Consent must be obtained from all participants. It is strongly recommended that you use the consent and recruitment templates available on our forms web page. Consent can be collected electronically, verbally, or by use of a paper consent form. The consent form must include the purpose of the project, study title, a description of the procedures including duration of participation, the risks/benefits of participation, PI name and contact information, IRB contact information (330-672-2704), statement of voluntary participation, and description of privacy and confidentiality.

Research personnel management - The PI is responsible for ensuring all personnel are trained on the project/lab procedures and have completed CITI training and are accounted for using Appendix A1. Changes to personnel, other than PI, do not need to be reported to the IRB.

You are responsible for ensuring your research is compliant with all relevant KSU policies. This includes, but is not limited to, compliance with FERPA, Title IX, and HIPAA policies as well as the On Campus Activities Involving Minors policy (UP 3342-5-19).

Q2 Project title

Must match the title on the consent form.

Q6 PI first and last name

Must be a faculty or professional staff person.
Q11 Are the research procedures limited to the survey or educational testing (cognitive, diagnostic, aptitude, achievement) of autonomous adults?

○ Yes (1)

○ No (2)

Skip To: Q31 If Are the research procedures limited to the survey or educational testing (cognitive, diagnostic,... = No

Q24 I understand and acknowledge that the research will be conducted according to the Kent State University Administrative Policy Regarding Research Involving Human Subjects (10-02.1).

The policy can be viewed at (copy and paste the link into a separate browser window): https://www.kent.edu/policyreg/administrative-policy-regarding-research-involving-human-subjects-0

○ Yes (1)

○ No (2)

Skip To: Q31 If I understand and acknowledge that the research will be conducted according to the Kent State Univ... = No
Q18 I am a...

Only faculty members and professional staff who are full-time university employees are eligible for PI status. Investigations conducted by university students must be supervised by a faculty person.

- faculty person or a professional staff person. (1)
- student working under the supervision of a faculty person and completing this form on behalf of that faculty person. (2)
- student working without the supervision of a faculty person. (3)

Q20 You indicated that you are a student completing this form without the support of a faculty person.

In order to obtain IRB approval you must submit an application under the supervision of a faculty person.

The KSU PI policy can be found at (copy and paste the following link into a new browser window): https://www.kent.edu/research/office-research-compliance/irb-help

Please select next to receive your determination email.
Q7
You indicated that you are student completing the form on behalf of a faculty person.

Please type the faculty PI's full @kent.edu email address below.

________________________________________________________________

Page Break

Q21 Exclusionary questions

Q29 Are you receiving federal funds to support this research?

- Yes (23)
- No (24)

Skip To: Q31 If Are you receiving federal funds to support this research? = Yes

Page Break

Q12
Does the research involve an intervention that includes the manipulation of the subject or the subject's environment for the purpose of changing their behavior(s), processes, or other endpoint(s)?

More information on excluded interventions can be found at (copy and paste the link into a new tab): https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html

Examples of interventions include the performance of cognitive tasks, performing tasks under
noise conditions, completing puzzles or decision making tasks, or playing games.

- Yes (1)
- No (2)

**Skip To: Q31 If Does the research involve an intervention that includes the manipulation of the subject or the su... = Yes**

Q8 Does the target population include children (under the age of 18), pregnant women, adults who may not be legally/mentally/cognitively competent to provide consent, or prisoners?

- Yes (2)
- No (3)

**Skip To: Q31 If Does the target population include children (under the age of 18), pregnant women, adults who may... = Yes**

Q9 Do research procedures include access to, or the collection of Protected Health Information (HIPAA compliance) or Student Educational Records (FERPA compliance).

*Information on HIPAA and FERPA can be found at (copy and paste links into a new browser window):*

- HIPAA: https://www.kent.edu/compliance/hipaa
- FERPA: https://www.kent.edu/registrar/ferpa

- Yes (1)
- No (2)

**Skip To: Q31 If Do research procedures include access to, or the collection of Protected Health Information (HIPA... = Yes**
Q10 The information is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects
AND Any disclosure of the subject's responses outside of the research could reasonably place the subject at risk of criminal or civil liability or could be damaging to the subject's financial standing, employability, or reputation.

- Yes (1)
- No (2)

Skip To: Q31 If The information is recorded in such a manner that subjects can be identified, directly or through... = Yes

Page Break

Q28 Will the research expose participants to discomfort or distress beyond that normally encountered in everyday life?

- Yes (23)
- No (24)

Skip To: Q31 If Will the research expose participants to discomfort or distress beyond that normally encountered... = Yes

Page Break

Q13 Does the research involve the use of deception?

- Yes (1)
- No (2)

Skip To: Q31 If Does the research involve the use of deception? = Yes
Q26 Will any research activities be performed outside of the United States or territories?

- Yes  (1)
- No  (2)

Skip To: Q31 If Will any research activities be performed outside of the United States or territories? = Yes

Q27 Does a project team member have a conflict of interest?

- Yes  (1)
- No  (2)

Skip To: Q31 If Does a project team member have a conflict of interest? = Yes

Q23 Are any external personnel or external institutes (including third party data collection organizations) engaged in the research?

An institute or individual becomes engaged in research when it intervenes or interacts with living individuals for research purposes or obtains individually identifiable private information for research purposes. Additionally, an institute or individual is considered to be engaged in research whenever they receive a direct federal award to support human subjects research.

- Yes  (1)
- No  (2)

Skip To: Q31 If Are any external personnel or external institutes (including third party data collection organizations) engaged in the research? = Yes
Q22 Research Procedures

The following information is used by the IRB and Office of Research Compliance for multiple reasons. To help us make a fully informed decision should you wish to amend the project. It will also help us provide direction to participants should they reach out to us with questions. It will be used to help us further develop the self-determination process. It will help provide metrics that can be used to inform research initiatives.

Q14
Briefly describe the purpose and topics of the research.

________________________________________________________________________

Q16 Briefly describe your recruitment strategy.

________________________________________________________________________

Q17 Briefly describe the survey or educational test. Include where and how it will be administered.

________________________________________________________________________

Q32 Please upload your consent form.
Q35 PI Assurance Statements: The information provided is accurate and complete. Anyone serving as research personnel have been or will be trained (including the completion of CITI training) prior to engaging in research activities. Records will be maintained for at least three years from the date the study is completed. I will contact the Office of Research Compliance if my research plans change. I will contact the Office of Research Compliance if the PI leaves KSU to amend or terminate the research. I will contact the Office of Research Compliance if an unexpected outcome or adverse event is experienced. Agree to inform all co-investigators/key personnel assisting in the conduct of the research of their obligation in meeting the above commitments. A consent document will be provided to participants.

○ TRUE to all (23)

○ NOT TRUE to any (24)

Q31 Your study is not eligible for self determination based on one or more of your responses.

What must you do next:
In order to obtain IRB approval, you must complete a level I or level II/III form.

Level I forms can be submitted directly to researchcompliance@kent.edu.

Level II/III forms must be submitted to a discipline specific reviewer.

Forms, training, and other helpful information can be found at: https://www.kent.edu/research/office-research-compliance

You must select next to receive your determination email.
Q34 Your study has been exempted. You will receive a formal email. Please review this email carefully, it includes important information.

You must select next to receive your determination email.