IRB Determination form Review Path
(This document is for information only, to obtain a determination you must complete the determination form)

**Is the project a systematic investigation?**
Systematic investigation means the implementation of rule-based methods that are repeated with multiple participants in a consistent manner across the participants. Alternatively, the method may be implemented according to specified rules with a single participant for types of investigations. For example, case studies designed for publication are systematic investigations of a single person.

**Will the conclusions contribute to generalizable knowledge?**
Generalizable knowledge is data and/or conclusions that can be applicable beyond a particular place, person, or setting. Activities that are typically not generalizable include practicums, biographies, oral histories, service or course evaluations (unless they can be generalized to other individuals), services or concepts where it is not the intent to share the results beyond KSU or the supporting agency, classroom exercises to fulfill course requirements or to train students in the use of a method or device, quality assurance activities where it is not the intention to share the results beyond KSU or the supporting agency.

**Does the research involve obtaining information about living individuals?**
Human subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or the use of identifiable information.

**Does the research involve intervention or interactions (e.g., interviews, examinations, questionnaires) with persons?**
Intervention is defined as physical procedures by which data are gathered (for example, venipuncture) and/or manipulations of the subjects or the subject's environment that are performed for research purposes. Interaction means communication or interpersonal contact between investigator and subject.

Regardless of determination all research must be consistent with the Belmont Report.
IRB Determination Form

This survey is currently LOCKED to prevent invalidation of collected responses! Please unlock your survey to make changes.

Default Question Block
This module is designed to help you determine if your project is considered human subjects research as defined by the Department of Health and Human Services (DHHS).

We recommend reviewing the Human Subjects Research Decision Charts that are available on DHHS' webpage to help inform your decisions.

Activities that meet the definition of human subject research require the submission of an IRB application. If you know your project meets the human subjects research definition, you do not need to complete this module and you must submit a Level I or Level II/III form.

Activities that are determined to not meet the definition of human subjects research do not require the submission of an IRB application. *Upon completion of this module you will receive an email notifying you of the results.

Regardless of the determination, you are responsible for ensuring your research is conducted ethically, in accord with the principles of the Belmont Report and other ethical standards within your discipline. Other federal, state, KSU policies and local laws and/or regulations may apply that are not under the oversight of the IRB; please consult with your academic department to learn more.

**If you are a student, this module is to be completed under the direction of a faculty member. Student research projects must be approved and conducted under the supervision of a faculty advisor.**

If you have any questions or need assistance, please contact us at researchcompliance@kent.edu.

**Project title.**
Q2

Research is defined by DHSS as a systematic investigation designed to develop or contribute to generalizable data.

Q3

Is the project a systematic investigation?

Systematic investigation means the implementation of rule-based methods that are repeated with multiple participants in a consistent manner across the participants. Alternatively, the method may be implemented according to specified rules with a single participant for types of investigations. For example, case studies designed for publication are systematic investigations of a single person.

- Yes
- No

Condition: No Is Selected. Skip To: Activity is not research as defined by...

Condition: Yes Is Selected. Skip To: Will the conclusions contribute to ge....
Q4

Will the conclusions contribute to generalizable knowledge?

Generalizable knowledge is data and/or conclusions that can be applicable beyond a particular place, person, or setting.

Activities that are typically not generalizable include practicums, biographies, oral histories, service or course evaluations (unless they can be generalized to other individuals), services or concepts where it is not the intent to share the results beyond KSU or the supporting agency, classroom exercises to fulfill course requirements or to train students in the use of a method or device, quality assurance activities where it is not the intention to share the results beyond KSU or the supporting agency.

- Yes
- No

Condition: No Is Selected. Skip To: Activity is not research as defined b....

Condition: Yes Is Selected. Skip To: Human subject means a living indivi....
Q9  Activity is not research as defined by DHHS, so 45 CFR 46 does not apply and you do not need to take further IRB action.

Please be aware that you are responsible for ensuring your research is conducted ethically (i.e. in accord with the Belmont Report). Other federal, state, KSU policies and local laws and/or regulations may apply that are not under the oversight of the IRB; please consult with your academic department to learn more.

You will receive an email with a unique identifying number. Please read this email carefully and store it in your research files. We will only be able to access your file (should it be necessary) using this identifying number.

Thank you for completing this determination module. If you think you have received this determination in error, please let us know.

If you have any questions, please contact us at researchcompliance@kent.edu.

YOU MUST CLICK THE NEXT BUTTON BELOW TO RECEIVE YOUR DETERMINATION EMAIL THAT INCLUDES YOUR UNIQUE IDENTIFYING NUMBER.

Condition: Activity is not research as... Is Displayed. Skip To: End of Survey.

Q5  Human subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or the use of identifiable information.
Q8  Does the research involve obtaining information about living individuals?

- Yes
- No

Condition: No Is Selected. Skip To: Activity is not human subjects research....

Condition: Yes Is Selected. Skip To: Does the research involve intervention....

Q6  Does the research involve intervention or interactions (e.g., interviews, examinations, questionnaires) with persons?

- Yes
- No

- Intervention is defined as physical procedures by which data are gathered (for example, venipuncture) and/or manipulations of the subjects or the subject’s environment that are performed for research purposes.

- Interaction means communication or interpersonal contact between investigator and subject.
Q7 Does the data contain identifiable private information?

Private information includes information about behavior that occurs in a context in which an individual can reasonable expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonable expect will not be made public (for example, a medical record). OHRP generally considers private information or specimens to be individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individual by the investigator(s) either directly or indirectly through coding systems.

- Yes
- No

Condition: No Is Selected. Skip To: Activity is not human subjects research....

Condition: Yes Is Selected. Skip To: Activity is human subjects research, ....
Q11 Activity is not human subjects research, so 45 CFR 46 does not apply and you do not need to take further IRB action.

Please be aware that you are responsible for ensuring your research is conducted ethically (i.e. in accord with the Belmont Report). Other federal, state, KSU policies and local laws and/or regulations may apply that are not under the oversight of the IRB; please consult with your academic department to learn more.

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**YOU MUST CLICK THE NEXT BUTTON BELOW TO RECEIVE YOUR DETERMINATION EMAIL THAT INCLUDES YOUR UNIQUE IDENTIFYING NUMBER.**

Condition: Activity is not human subje... Is Displayed. Skip To: End of Survey.
Activity is human subjects research, so 45 CFR 46 does apply. You must submit a Level I or Level II/III form. If your project is being conducted under the oversight of another IRB, please submit the Inter-Institutional Authorization Agreement Request form.

You will receive an email with a unique identifying number. You do not need to refer to this number when submitting your application for IRB approval. Please read this email carefully, it will describe what steps you need to take next. Please store it in your research files. We will only be able to access your file (should it be necessary) using this identifying number.

Thank you for completing this determination module. If you think you have received this determination in error, please let us know.

If you have any questions, please contact us at researchcompliance@kent.edu.

YOU MUST CLICK THE NEXT BUTTON BELOW TO RECEIVE YOUR DETERMINATION EMAIL THAT INCLUDES YOUR UNIQUE IDENTIFYING NUMBER.

Condition: Activity is human subjects ... Is Displayed. Skip To: End of Survey.