

IRB Determination Form

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Q1 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.



Q14 If you are a student, enter your faculty/project advisor's @kent.edu email address.

Q15 If you are a student, enter your first and last name.

End of Block: Default Question Block

Start of Block: Block 1

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 (1)

☐ No (2)

Skip To: Q9 If Is the project a systematic investigation? Systematic investigation means the implementation of... = No

Skip To: Q4 If Is the project a systematic investigation? Systematic investigation means the implementation of... = Yes

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 apply 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 (1)

☐ No (2)

Skip To: Q9 If Will the conclusions contribute to generalizable knowledge? Generalizable knowledge is data and... = No

Skip To: Q5 If Will the conclusions contribute to generalizable knowledge? Generalizable knowledge is data and... = Yes

Page Break

Q9 Activity is not human subjects 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.

Skip To: End of Survey If Activity is not human subjects research as defined by DHHS, so 45 CFR 46 does not apply and you d... Is Displayed

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Q5

Definitions: *About individuals means that the information must be about a person. (example of not asking about people - asking transportation officials to describe transportation policies and procedures)* *Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording taking place, and which the individual can reasonably will not be made public. (example, information from a student record)* *Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.* *Identifiable biospecimens is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.*

Q8 Does the research involve obtaining, using, studying, analyzing, or generating identifiable private information about or identifiable biospecimens from living individuals?

☐ Yes (1)

☐ No (2)

Skip To: Q11 If Does the research involve obtaining, using, studying, analyzing, or generating identifiable private information about or identifiable biospecimens from living individuals? = No

Skip To: Q6 If Does the research involve obtaining, using, studying, analyzing, or generating identifiable private information about or identifiable biospecimens from living individuals? = Yes

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Q6

Does the research involve obtaining information about or biospecimens from living individuals through intervention or interaction with the individual, and using, studying, or analyzing the information or biospecimens living individuals?

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.

☐ Yes (1)

☐ No (2)

Skip To: Q10 If Does the research involve obtaining information about or biospecimens from living individuals thr... = Yes

Skip To: Q7 If Does the research involve obtaining information about or biospecimens from living individuals thr... = No

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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 taking place, and which the individual can reasonably will not be made public. (example, information from a student 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 (1)

☐ No (2)

Skip To: Q11 If Does the data contain identifiable private information? Private information includes informatio... = No

Skip To: Q10 If Does the data contain identifiable private information? Private information includes informatio... = Yes

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

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Skip To: End of Survey If Activity is not human subjects research, so 45 CFR 46 does not apply and you do not need to take... Is Displayed

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Q10 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.

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