**Guide to Exempt Research**

1. **GENERAL OVERVIEW**

The federal regulations allow certain minimal risk research activities involving human subjects to be exempt from full or expedited Institutional Review Board (IRB) review processes. This document is intended to help investigators understand the Kent State University IRB requirements for exempt research. This guidance does not apply to non-exempt research. It includes three appendices, (1) categories of level I research, (2) FAQs, and (3) information on Self-Determinations.

Exempt research is sometimes referred to as Level I research and is not exempt from IRB review and approval. This means that exempt research may not commence without IRB review and approval. All exempt research that involves interaction or intervention with a human subject must involve a consent process, unless waiving it can be justified.

Exempt research must be conducted according to KSU policy, terms and conditions of research funding agreements, other applicable laws and regulations, and for compliance with programs that are outside of the IRB’s purview. Exempt research must abide by sound ethics, including those described in *The* *Belmont Report*.

1. **FORMS**

Level I and Self-Determination Forms:investigators can apply for exemption via a “paper” form or an online self-determination program. “Paper” forms are required for any exempt research not-eligible for self-determination and must be submitted to a discipline specific review or researchcompliance@kent.edu. Appendix 3 describes research that may go through the self-determination process. To be considered exempt the research must:

* be minimal risk (the research will not expose participants to discomfort or distress beyond that normally encounter in daily life),
* be limited to one or more of the activities described in Appendix 1,
* not collect information that is both identifiable and sensitive, and
* not specifically target prisoners for inclusion.

Adverse and Non-compliant Event Forms:all instances of non-compliant activity and adverse events must be reported to the IRB per the Human Subjects Adverse Events and Human Subjects Non-compliance policies (presently under review by General Counsel). Adverse and Non-compliant Event forms must be submitted to researchcompliance@kent.edu.

Amendment Forms: all amendments to an exempt study after initial IRB approval must be reviewed and approved by the IRB prior to implementation. If a change disqualifies the research from exempt status, you will be given instructions on how to proceed. Amendment forms must be submitted to researchcompliance@kent.edu.

Continuing Review Form (and Approval Terms): exempt studies do not expire, so you do not need to file continuing review forms for exempt studies. The ORC performs file maintenance and periodically sends closeout inquiries to investigators. If you receive a closeout inquiry, follow the instructions listed in the email to continue the study or close it.

Personnel (including personnel changes) Forms: PI’s are responsible for managing research personnel; Appendix A1 can be used. This includes managing access to human subjects and identifiable data and ensuring personnel are properly trained; this includes the requirement for all personnel to have a current CITI certificate. Only external personnel need to be reported to the IRB (using Appendix B). See also “CITI and Training.”

1. **OTHER CONSIDERATIONS**

CITI and Training:all personnel involved in human subjects research must complete the appropriate CITI training course and be appropriately trained to conduct the activities for which they are responsible.

Compliance Requirements that are Outside of the IRB’s Purview**:** as previously indicated, certain projects may have compliance needs that lay outside of the purview of the IRB. As a courtesy the IRB and the Office of Research Compliance may help you obtain the necessary reviews, but it is the PI’s responsibility to ensure all applicable regulatory requirements are addressed. Common compliance needs include:

* FERPA review, any study that involves access to or uses FERPA protected information must be also be approved by the Registrar, <https://www.kent.edu/registrar/ferpa>.
* HIPAA review, any study that involves access to or use of PHI or a waiver and/or alteration of HIPAA authorization must also be approved by HIPAA Privacy Officer and HIPAA Security Officer, <https://www.kent.edu/compliance/hipaa>.
* Institutional Biosafety Committee review, <https://www.kent.edu/compliance/research-safety-and-compliance>.
* Title IX reporting requirements apply to researchers, <https://www.kent.edu/sss>.
* Terms described in a grant or contract.

Consent:consent is the hallmark of human subjects research and all exempt research that involves an interaction or intervention must include a consent process unless waiving it can be justified. Simplified consent forms can be used for exempt research, but should include the following:

* a statement that the project is being conducted for research
* include the PI name and contact information and project title
* a statement about voluntary participation
* a statement about confidentiality and privacy
* a description of the procedures
* risks and benefits
* if applicable, compensation
* any other information that is important for subjects to know

Deception:is only permissible under category 3 when the participant is prospectively informed they will be deceived. Debriefing is required. Any other form of deception must go through the level II/III process.

Duration of approval: exempt studies do not expire, so you do not need to file continuing review forms for exempt studies. The ORC performs file maintenance and periodically sends closeout inquiries to investigators. If you receive a closeout inquiry, follow the instructions listed in the email to continue the study or close it.

Multi-institute projects:the IRB rarely enters into formal IRB agreements for exempt projects. If working with an investigator from another institution, they should contact their IRB. The IRB or Office of Research Compliance will provide guidance during the review process.

Recruitment:as with consent, a recruitment process must be used for any exempt study that involves interaction or intervention with a subject. Consent forms may be used as recruitment scripts only when appropriate.

Special Populations:

* Children: may be included in exempt research except for all procedures under Category 3 and surveys and interview under Category 2.
	+ Parental consent is required unless waiving it is justified.
* Prisoners: may be included in exempt research, but only if they are incidentally included when targeting a broader population.
* Other: protections for other populations that may need special considerations must be well planned when preparing an IRB application even if such population is not granted special protections under the federal regulations. If a population alone raises the risk profile of a project you may need to consider a level II/III application. Certain circumstances may make a project not eligible for exemption; for example, a population with limited cognitive abilities may not be able to understand the consent form and therefore consent could be inhibited to the point where exempt review is inappropriate. Contact the Office of Research Compliance for more information.

Students as Research Subjects:all projects must adhere to the [students as research subjects policy](https://e3a63586-a-4304462c-s-sites.googlegroups.com/a/kent.edu/division-of-research-and-sponsored-programs-intranet/home/file-cabinet/Students%20as%20research%20subjects.pdf?attachauth=ANoY7cp2HFEmINMRfOugWqX1298mG_a1tmuKVbrRHZ2l9VrGVCJnBcGhURLmB3-EpzwfWzakKbzVGoWK6SRGs6TdqXylUd1m-STHGW2qW1dzZrgZphVxVRrCdoGebGWOUR9pQobUoqkh4HYKQpX8zkjDp02l030MsOzT_jDNdF8z8Rn-_YQHwz7Shg78npNirSaBtf58Tm7MvPYsH3dn9SYSB0Uny-B0Wlr8LOMysQxrFaDtVZJ3xDubCs1nXjxgstWx5Tjd6J1MmO1T__lR4PufKhL3qFIq5CyKTSmQf5kls3SgDRwI9iqihXPbjT_bllIG7dF1eBr_&attredirects=0).

**Appendix 1, Categories of Exempt Research**

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| **Levels of Review – Level I/Exempt Category**  |
| Level I/Exempt Category | Notes |
| (**category 1**)**Research involving normal** **educational practices performed in educational settings** 1. **Conducted in established/commonly accepted educational settings, AND**
2. **Research is on the effectiveness or comparisons of instructional techniques, curriculum, or classroom management techniques, AND**
3. **The research is not likely to have an adverse impact student ability to learn required content or the evaluation of the teacher**
 | If data collection involves interviews, observations, or surveys that go beyond the scope of an educational activity and involve children a level II/III form is required. If the interviews/observations/surveys go beyond the scope of the activity and involve adults they must also be described in exemption category 2. Any research activity involving minors that is being performed in an educational setting requires a letter of support from the official in charge of the setting (principal, superintendent or equivalent).  |
| **(category 2) Research that only includes surveys, interviews (focus groups), educational tests, and observation of public behavior (including audio/visual recording)**1. **Information recorded in a non-identifiable manner, OR**
2. **Information recorded would not place subjects at risk or harm**
 | * Identifiers may be collected **unless**: Disclosure of identifiable responses could place subjects at risk (legally, or damage financial standing, employability, or reputation) OR data sensitivity increases overall risk
* Indirect identifiers are more than one data element that can be used in combination or with other information to ascertain someone’s identity. Indirect identifiers must be carefully considered when which IRB application to complete
* Identifiers should only be collected when necessary
* Linking data to additional PII is not permissible under this category (see level II, category 7)
	+ No interventions under this category (see exempt category 3 or level II category 7)
	+ No surveys, interviews, or focus groups with children (see level II, category 7)
	+ No observations with children if the researcher will participate in the observed activities
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| **(category 3) Benign behavioral interventions (and information collection is limited to verbal or written responses, observation, data entry, or A/V recording)**1. **Information recorded in a non-identifiable manner, OR**
2. **Information recorded would not place subjects at risk or harm**
 | * Intervention is brief (under 4 hours) even if data collection period is longer
* Benign means the procedures are harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subject, and the procedures will not be embarrassing or offensive.
* Behavioral interventions are limited to communication or interpersonal contact or performance of cognitive, intellectual, educational, or behavioral tasks, or the manipulation of the subject’s physical, sensory, social or emotional environment.
* Deception is permitted if participants are prospectively informed they will be deceived. Debriefing is required.
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| **(category 4) Use of secondary specimens/data** 1. **All data/specimens exist at time of IRB submission, AND**
2. **Recorded with NO identifiers (including no link/code/key), OR is publicly available**
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| **(category 5) Research and demonstration projects that are conducted or supported by a Federal Department or Agency or otherwise subject to the approval of department or agency heads, AND are designed to study, evaluate, improve or otherwise examine public benefit or service programs.**  | This category is typically reserved only for use by the Federal government. |
| **(category 6) Taste and food quality evaluation and consumer acceptance studies,** * 1. **If wholesome foods without additives are consumed, or**
	2. **If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.**
 | This category is rarely used. |

**Appendix 2, FAQs**

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| **FAQ’s** |
| 1. ***Does audio/visual recording of interviews mean that my study cannot be exempt?*** No. Audio/video recording is permitted activity in most cases. However, if audio/video recording increases risk, you may need to submit a level II/III form. An example of audio/video recording increasing risk would be an interview in which employees disclose negative opinions of their supervisors.
2. ***Can I have prisoners as participants in my Exempt research?*** ONLY if they are incidentally included as part of a broader subject population.
3. ***What does “normal education practice” mean?*** A normal educational setting and practice may include a class in a grocery store, professional development workshops, or skills development in children’s summer camps. It is not necessarily limited to primary and secondary public/private educational settings. However, studies that involve new experimental educational practices or settings may not fit into this category and may need to be reviewed at a higher level.
4. ***If my survey is completely anonymous but may pose a risk to participants, can it still be exempt?*** Maybe. In the event that a disclosure of a humans subject’s responses outside the research could reasonably place them at risk but the data are completely anonymous, exempt category 2 may apply. A determination for a higher level of review may be made at the discretion of the IRB on a case-by-case basis. However, even when responses are anonymous, if the study presents a risk of causing distress to the subject, the IRB may determine that review of the study by an expedited or full board procedure is appropriate. Example: An anonymous online survey about suicidal ideation.
5. ***Can my study be exempt in more than one category?*** Yes. All research activities that involve human subjects must fit within one or more of the exempt categories in order to be given an exempt determination. If any aspect of the research falls outside of a category of exemption, complete a level II/III form.
6. ***Do “exempt” studies have to be reviewed by the IRB?*** Yes. Exempt studies are so named because they are exempt from some, but not all regulations. They are not exempt from state laws, institutional policies, or the requirements of ethical research.
7. ***Can my study be exempt if it involves documents, records, or biological specimens that do not yet exist and will be collected as they become available?*** No. In order for a research study to be exempt, all data, documents, specimens, and records must already exist at the time the PI submits the research protocol. Prospective data collection, i.e. data collected as they become available, will need to be reviewed via a level II/III form.
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**Appendix 3, Self-Determination Exclusions**

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| **Self-Determinations Exclusions** |
| 1. **PROGRAM DESCRIPTION**

The Self-Determination program provides investigators the opportunity to receive an IRB determination through an online process that is efficient yet does not compromise human subjects protections. As part of the application process the PI affirms that the information provided is accurate and complete, they will have reviewed this guidance document, research personnel will be appropriately trained, the research will be performed under their oversight, study records will be maintained in a way that maintains privacy and confidentiality and for at least three years after the study is completed, a consent process will be used, any supplemental approvals will be obtained prior to initiating the research. The program can be tested by selecting “wanting to learn more by testing the form” at the end of the first page. 1. **EXCLUSIONS**

Not all exempt research qualifies. If your project involves the following excluding factors a “paper” submission is required. * The research is not limited to category 1 or 2 criteria.
* The study is externally funded or there will be an attempt to obtain external funding for the project (including contracts and other external mechanisms).
* The study is not minimal risk; this includes the collection of information that is both sensitive and identifiable.
* The target sample includes any of the following, children, prisoners, active military, individuals with limited language skills, individuals with impaired decision-making skills, or any other population that may require enhanced protection or be otherwise vulnerable.
* External personnel are engaged in research activities (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>).
* The research will be conducted outside of the US or enroll subjects residing outside of the US or otherwise contradict a cultural norm.
* The research involves access to Protected Health Information.
* A member of the study team has a conflict of interest.
* If applicable, audio and/or video recording will be conducted for a purpose other than transcription.
* Failing to endorse that the research will be FERPA compliant.
1. **POST APPROVAL**

After receiving approval through this program you are expected to communicate with the IRB as usual. Please remember to report non-compliant and/or adverse events as well as amendments to the IRB via the appropriate form.  |