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| **Guidance on Level of IRB Review**  This document addresses commonly asked questions about level of review/what application process may be required and is divided into 4 sections:   1. KSU and Regulatory positions 2. Level I/Exempt Research 3. Level II/Expedited Research    1. Categories of expedited research can also be found at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html> 4. FAQs   When determining level of review, start with the level I application. If any element of your research does not meet a category of exemption or presents greater than minimal risk, complete the level II/III form.  Level III review is conducted for any project that presents greater than minimal risk or does not meet the regulatory categories for level I or level II review. Additionally, any Institutional Review Board (IRB) member has the authority to request level III review of a protocol regardless of the procedures.  Obtaining compliance approval with processes that are outside of the purview of the IRB is the responsibility of the Principal Investigator. These processes include, but are not limited to:   * HIPAA compliance: Privacy Officer reviews any access to PHI. <https://www.kent.edu/compliance/hipaa> * HIPAA compliance: IS Security reviews storage of PHI <https://www.kent.edu/compliance/hipaa> * Institutional Biosafety Committee: reviews the use of synthetic or recombinant DNA and other biohazardous materials (for example, human blood or tissue) <https://www.kent.edu/compliance/biological-safety> * FERPA compliance review is conducted by the Registrar’s Office <https://www.kent.edu/registrar/ferpa> * University Minors Policy applies to activities involving minors <https://www.kent.edu/compliance/campus-activities-involving-minors> | | |
| **KSU and Regulatory Positions** | | |
| **Level I/Exempt – IRB Permissible Research** | **Level II/Expedited – IRB Permissible Research** | **Notes** |
| Research must only present minimal risk and is limited to one or more exempt categories–minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. | Research must present no more than minimal risk and is limited to one or more categories of expedited research and may involve procedures that are otherwise approvable as exempt. | Level III review is conducted for any project that presents greater than minimal risk or does not meet the regulatory categories for level I or level II review. Additionally, any IRB member has the authority to request level III review of a protocol regardless of the procedures. |
| Sensitive information may be collected only if the participant and associated data is anonymous and the research presents only minimal risk. | Sensitive information may be collected so long as it does not present more than minimal risk. | Sensitive data is any data for which any disclosure of the responses outside of the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects’ financial standings, employability, insurability, or reputations. |
| Consent is required unless waiving it is justified. | Consent is required unless waiving it is justified. | A simplified consent form and process may be used for exempt research. Parental consent must be obtained (unless waiving it is justified) for research that includes children. |
| Special populations   * Children: allowed to include children, except in category 3 research and surveys and interviews conducted under category 2 * Pregnant women: allowed under any category * Prisoners: allowed, but only if they are incidentally included as part of a broader recruitment population | Special Protections   * Children: allowed under any category * Pregnant women: allowed under any category * Prisoners: allowed under any category | Protections for other special populations must be considered when developing research procedures. These populations may include those who are mentally or cognitively impaired, some aging individuals, or socially and economically disadvantaged individuals. |

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| **Levels of Review – Level I/Exempt Category** | |
| **Level I/Exempt Category** | **Notes** |
| (C**ategory 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 on the students’ ability to learn the required content, or on 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/or 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 of harm** | * Identifiers may be collected unless: disclosure of identifiable responses could place subjects at risk (legally, or of damaging their 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 |
| **(Category 3) Benign behavioral interventions (wherein 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 of 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, or 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. |
| **(Category 4) Use of secondary specimens/data**   1. **All data/specimens exist at time of IRB submission, AND** 2. **Are recorded with NO identifiers (including no link/code/key), OR are publicly available** |  |
| **Levels of Review – Expedited/Level II** | |
| **Expedited/Level II Category** | **Notes** |
| (C**ategory 1**) **Clinical studies** | * Only those that do not need to be submitted to the FDA |
| **(Category 2) Research involving blood collection** | Limits/methods are as follows--otherwise level III review is required:   * Finger stick, heel stick, ear stick, or venipuncture * Frequency = no more than 2x/week * Healthy, non-pregnant adults, weighing >110 lbs--total blood volume not exceeding 550 mL in 8 weeks * Other adults or children--total volume not exceeding the lesser of 50 mL **OR** 3 mL/kg in 8 weeks |
| **(Category 3) Prospective collection of biological specimens for research purposes by non-invasive procedures** | Examples include:   * Hair or nail clippings in a non-disfiguring manner * Collection of teeth as exfoliated or if obtained during routine patient care where there is a need for extraction * Excreta or external secretions * Saliva collection |
| **(Category 4) Non-invasive clinical procedures** | * Procedures routinely employed in clinical practice * Not involving general anesthesia or sedation * Not involving procedures that use x-rays or microwaves * Medical devices must be cleared/approved for marketing * No more than moderate exercise |
| **(Category 5) Materials (including specimens) collected for research or non-research purposes** | * Materials may or may not currently exist * May record or keep identifiers, but plans must be in place to protect confidentiality * Includes a variety of materials such as medical records, pathology specimens, or some student records |
| **(Category 6) Use of audio, video, and photography for research purposes** | * Use of audio, video, or photography for research purposes that are not otherwise exempt * Audio, video, and image recordings are considered personally identifiable |
| **(Category 7) Individual or group characteristics or behavior** | * Research involving surveys, interviews (or focus groups), educational tests, or observation of public behavior that cannot be approved as exempt under category 2 * Human factors * Research on perception, cognition, motivation, identity, and other social and behavioral paradigms that are not otherwise exempt under category 3 * Any research involving educational practices that do not meet all three of the conditions listed in exemption category 1 |
| **Exempt/Level I 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.   1. ***Can I have prisoners as participants in my Exempt research?***   ONLY if they are incidentally included as part of a broader subject population.   1. ***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.   1. ***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.   1. ***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.   1. ***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 for the requirements for ethical research.   1. ***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. | |