**Common Rule Exempt Categories Worksheet**

Due to eIRB system limitations, temporary use of this worksheet is required to apply for Exempt Review under the new Common Rule (effective January 21, 2019).

Select one or more the following Exempt Review paragraphs. All research activities must fall under one or more of the categories and must be properly justified (i.e., meet all the requirements or restrictions listed).

Complete the questions for each applicable category and upload the completed version of this form to the Attachments section of your Exempt protocol. Also indicate in the eIRB answer box(es) that the worksheet has been uploaded.

After the final eIRB form changes are implemented, the answers provided here will need to be moved into eIRB. Further instruction and assistance will be forthcoming. Contact the IRB with any questions (977-7744, irb@slu.edu).

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| **PI Name**:  | IRB #:  |

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| [ ]  ***Exempt Category 1- Normal Education Practices***  |
| Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
| **See the eIRB form for important notes about this category.** |
| 1. **Explain how the research is part of the commonly accepted educational setting at the research site(s) you listed in Study Locations and how the research involves normal educational practices.**
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| 1. **Explain how the research involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.**
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| [ ]  ***Exempt Category 2- Interaction/Behavioral Research***  |
| Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review.*
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| **See the eIRB form for important notes about this category.** |
| 1. **Describe the type of educational test or procedure.**
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| 1. **Indicate which sub-item of this category describes the research data/information (2i, 2ii, or 2iii above) and describe how the study qualifies (more detailed information regarding the data in your study will be required in the Privacy and Confidentiality section of the eIRB form).**
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| [ ]  ***Exempt Category 3- Benign Behavioral Interventions*** |
| Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review.*
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| **See the eIRB form for important notes about this category.** |
| 1. **Justify how the research qualifies as a brief benign behavioral intervention.**
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| 1. **Indicate which sub-item of this category describes the research data/information (A, B, or C above) and briefly describe how the study qualifies (more detailed information regarding the data in your study will be required in the Privacy and Confidentiality section of the eIRB form).**
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| [ ]  ***Exempt Category 4- Secondary Data Analysis***  |
| Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:1. The identifiable private information or identifiable biospecimens are publicly available;
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under [HIPAA], for the purposes of “health care operations” or “research” as those terms are defined [by HIPAA] or for “public health activities and purposes” as described under [HIPAA]; or
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with the E-Government Act, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act.
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| **See the eIRB form for important notes about this category.** |
| 1. **State: type of and source(s) from which the data/specimens will be collected.**
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| 1. **Indicate which sub-item of this category describes the research data/information (i, ii, iii, or iv above) and briefly describe how the study qualifies (more detailed information regarding the data in your study will be required in the Privacy and Confidentiality section of the eIRB form).**

**NOTE:** Research involving sub-item iii will require a HIPAA waiver. Follow the instructions in the HIPAA section of the eIRB form. |
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