Human Subjects Protections and IRB Regulated Research

Presented by the Office of Research Compliance
Overview

• Exempt/level I research, (categories 1, 2 and 3)

• Expedited/level II research

• Full board/level III research

• Tips and questions at the end

See our guidance on level of review and template documents!
Exempt/Level I Research

Minimal Risk and entirely falls with any of the following categories

Can be submitted to discipline specific reviewer or researchcompliance@kent.edu
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 standing, employability, insurability, or reputation.

**Section 2 - Qualifying Statements**

1. The research will not expose participants to discomfort or distress beyond that normally encountered in daily life (minimal risk).
   - True  Not True

2. The research will not involve the collection of data that is both sensitive and identifiable.
   - True  Not True

3. The research does not target the inclusion of prisoners.
   - True  Not True

4. The research is not subject to FDA regulations
   - True  Not True

*If you have checked Not True to ANY of these qualifying statements, your research is NOT EXEMPT. Do not complete this application. You must submit a Use of Human Subjects in Research Application - (Level II/III).*
Educational Settings - Category 1 Exempt Research

i. The research will only be conducted in established or commonly-accepted educational settings.

ii. The research will only involve normal educational practices.

iii. The research is not likely to have an adverse impact on student learning of required content or assessment of the educators who provide instruction.
# Educational Settings - Category 1 Exempt Research

<table>
<thead>
<tr>
<th>Category 1 – Educational Practices Performed in Educational Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The research will only be conducted in established or commonly-accepted educational settings. <em>(Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms, after-school programs, preschools, vocational schools, alternative education programs, and other sites where educational activities regularly occur.)</em></td>
</tr>
<tr>
<td>True</td>
</tr>
<tr>
<td>Not True → Research is not exempt. Complete a <a href="#">Level II/III</a></td>
</tr>
<tr>
<td>2. The research will involve only <em>normal</em> educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Normal educational practices include established or innovative teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher. Normal educational practices are activities that could occur regardless of whether the research is conducted.</td>
</tr>
<tr>
<td>True</td>
</tr>
<tr>
<td>Not True → Research is not exempt. Complete a <a href="#">Level II/III</a></td>
</tr>
<tr>
<td>3. The research is not likely to have an adverse impact on student learning of required content or assessment of educators who provide instruction.</td>
</tr>
<tr>
<td>True</td>
</tr>
<tr>
<td>Not True → Research is not exempt. Complete a <a href="#">Level II/III</a></td>
</tr>
</tbody>
</table>

Explain how your research is considered to take place in a commonly accepted education setting, and involves normal educational practices. *(Include copies of any tests, questionnaires, recruitment scripts, etc. via email attachment when submitting the application. If you will be recruiting children from a school(s), you may not initiate recruitment until letter of support from the Principal or Superintendent has been filed with the Office of Research Compliance.)*
Educational Settings - Category 1 Exempt Research

Examples that qualify for category 1
• Research on the effectiveness of online education software
• Research on innovative methods (storyboarding, enhanced environments, “real-world” learning)

Examples that do not qualify for category 1
• A long intervention that detracts from the learning of required content (submit a level II/III form)
• Untested intervention that does not support regular curriculum (submit a level II/III form)
  • Both detract from required content

All research under this category may involve children.
Educational Tests, Surveys, Interviews, Observation of Public Behavior - Category 2 Exempt Research

Research that *only includes interactions* involving educational tests, surveys, interviews, and/or observations of public behavior (*including audio/video recording*).

i. Recorded in a non-identifiable manner, OR
ii. Disclosure would not place subjects at risk or harm, OR

*a clarification that interventions or linking to additional personally-identifiable information are not to be performed under this category.*
## Educational Tests, Surveys, Interviews, Observation of Public Behavior - Category 2 Exempt Research

<table>
<thead>
<tr>
<th>Category 2 - Research that only includes interactions involving Educational Tests, Surveys, Interviews, Public Behavior Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The research population includes <strong>CHILDREN</strong> (under 18 years old) and the research is limited to educational testing OR observation of public behavior where the investigator will not participate in the activities being observed. <strong>If the research does not involve children, check N/A.</strong> Research involving surveys or interviews with children, or observation of public behavior when investigators interact with children, does not qualify for exempt status under this category. Videotapes and photographs are typically considered identifiable. Any data collection that involves video recordings or photographs of subjects would be considered to have identifiers.</td>
</tr>
<tr>
<td>□ True</td>
</tr>
<tr>
<td>□ N/A – the research does not involve children.</td>
</tr>
<tr>
<td>2. The subject population only includes <strong>ADULTS</strong> (18 years and older) and the research will only involve educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews (including focus groups) or observation of public behavior (including audio or visual recording). <strong>Audio and/or visual recording is considered identifiable.</strong></td>
</tr>
<tr>
<td>□ True</td>
</tr>
<tr>
<td>□ Not True → Research is not exempt. Complete a <a href="#">Level II/III</a></td>
</tr>
<tr>
<td>□ N/A – the research does not involve adults.</td>
</tr>
<tr>
<td>i. The information <strong>will be recorded</strong> in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects. <strong>OR</strong></td>
</tr>
<tr>
<td>□ True</td>
</tr>
<tr>
<td>□ Not True → Research is not exempt. Complete a <a href="#">Level II/III</a></td>
</tr>
<tr>
<td>ii. Any disclosure of the human subjects' responses outside the research <strong>WOULD NOT</strong> reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.</td>
</tr>
<tr>
<td>□ True</td>
</tr>
<tr>
<td>□ Not True → Research is not exempt. Complete a <a href="#">Level II/III</a></td>
</tr>
<tr>
<td>3. Describe the educational test, survey, interview or observation procedure. <em>(Attach copy of tests, surveys questions, verbal scripts/protocols, recruitment scripts, etc. when submitting the application for review.)</em></td>
</tr>
</tbody>
</table>
Educational Tests, Surveys, Interviews, Observation of Public Behavior - Category 2 Exempt Research

Examples that qualify for category 2 research:
• Anonymous survey about drug use (indirect identifiers!)
• Identifiable survey about exercise habits (identifiers should only be collected when necessary)

Example that does not qualify for category 2 research:
• Identifiable survey about drug use (level II/III)
• Participants are asked to attend a substance abuse training program then respond to a survey (training is an intervention - may qualify for category 3)
Children may only be involved in category 2 research that is limited to the observation of public behavior when the investigators do not engage with subjects or manipulate the environment. Otherwise, a level II/III application is required – this is not a change.
Benign Behavioral Interventions- Category 3 Exempt Research

Research involving benign behavioral interventions with individuals who prospectively agree and information collection is limited to verbal or written responses or A/V recording, and...

i. Recorded in a non-identifiable manner, OR
ii. Disclosure would not place subjects at risk or harm
Benign Behavioral Interventions- Category 3 Exempt Research

It’s not that simple!

✓ Benign means
  ✓ harmless, painless, not physically invasive and
  ✓ not likely to have a significant adverse lasting impact on the subject and
  ✓ the intervention won’t be embarrassing or offensive

✓ Behavioral interventions are limited to
  ✓ communication or interpersonal contact or
  ✓ performance of cognitive, intellectual, educational, or behavioral task, or
  ✓ manipulation of the subject’s physical, sensory, social, or emotional environment

✓ Intervention must be brief in duration (up to 4 hours), even if subsequent data collection takes longer
# Benign Behavioral Interventions - Category 3 Exempt Research

<table>
<thead>
<tr>
<th>Category 3 - Research involving benign behavioral interventions</th>
<th>True</th>
<th>Not True → Research is not exempt. Complete a Level II/III</th>
</tr>
</thead>
<tbody>
<tr>
<td>The subject population only includes ADULTS (18 years of age and older) and the research is limited to brief, benign behavioral interventions. <em>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.</em> 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. Brief means 4 hours or less.</td>
<td>True</td>
<td>Not True → Research is not exempt. Complete a Level II/III</td>
</tr>
<tr>
<td>Data collection procedures are limited to verbal or written responses, data entry, or observation, including audio/visual recording.</td>
<td>True</td>
<td>Not True → Research is not exempt. Complete a Level II/III</td>
</tr>
<tr>
<td>The information will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects. <strong>OR</strong> 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, or reputation.</td>
<td>True</td>
<td>Not True → Research is not exempt. Complete a Level II/III</td>
</tr>
<tr>
<td>Describe the intervention and associated data collection procedure.</td>
<td>Attach associated tests, surveys, verbal scripts/protocols, recruitment scripts, SOP’s etc. when submitting this form for verification.</td>
<td></td>
</tr>
</tbody>
</table>
Benign Behavioral Interventions- Category 3 Exempt Research

Examples that qualify for category 3 research:
• Subjects attend an innocuous 30 minute presentation and are interviewed at multiple time points afterward
• Subjects complete puzzles under moderate noise conditions

Examples that do not qualify for category 3 research:
• Subjects watch 30 minute video that is designed to induce lasting stress then complete surveys (level II/III application)
• Small amounts of blood are collected via finger-stick procedures (level II/III application)

No research under this category may involve children. A level II/III application is required.
Additional information on exempt/level I research

Applicability of subparts (special protections)

- **Prisoners**: can be included in exempt research, but only if they are incidentally included as part of a broad population
- **Children**: no benign interventions, surveys or interviews (must obtain parental consent)
- **Pregnant Women and Fetuses**: can be included in any category of exempt research

Deception (for category 3)

if the subject is prospectively informed that they will be deceived - debriefing is still required

Audio and visual recording for category 1, 2 and 3

of interviews, observation of public behavior, and benign interventions

Online self-determination pilot and additional consent templates
Expedited/Level II research

- No more than minimal risk and any part of the project falls within any of the following categories
- Must be submitted to a discipline specific reviewer
- Most projects are approved for three-year terms

#1 - Clinical Studies
#2 - Collection of Blood Samples
#3 - Pros collection of Bio Specimens
#4 - Data through non-invasive procedures.
#5 - Materials (Data, documents, records or specimens collected for non-research purposes)
#6 - Data from voice, video, digital or image recordings
#7 - Individual or group characteristics
Full Board/Level III research

• More than minimal risk or does not meet any of the approval Level I or Level II categories of research
• Must be submitted to a discipline specific reviewer
• ORC assigns to an agenda, investigators attend meeting
• Must be reviewed at least annually
Consent

• Process of informing subjects – essential elements
• Focus on need to know information – no theoretical background
• Must be appropriate to the project – verbal, written
• Must be appropriate to the subjects
• Use the templates!
Common comments

Application materials are not consistent *(differences among recruitment, application and consent materials)*

Confusing privacy, confidentiality, and anonymity

Not responding to a question/addressing requested content

Consent form or materials are difficult to understand

Not properly identifying an intervention
Tips

Not considering other KSU policies in advance of submission

Don’t wait until the last minute

Have a friend or family member read your forms
Questions?

Where can I access forms? – www.kent.edu/research

How long does review take? – 2-6 weeks, it may take longer for complex or incomplete submissions or during busy periods
Thank You.

www.kent.edu