Panelists: Drs. Jeff Tysinger, Jonathan Hilpert, Kymberly Harris, and Cordelia Zinskie (IRB reviewers for the COE)

**Overall comment:** There are 12 IRB reviewers in the COE. Reviewers are typically willing to advise people BEFORE they submit a protocol if they have questions.

I. **Purpose of the IRB:** IRB protects rights of human participants to ensure there is no bias/coercion. Institutions need to be compliant or risk losing federal grants. IRB also protects students and researchers against accusations of bias (e.g., you gave me a bad grade because I chose not to participate in your study). Need outside reviewers to assess the risk because we ourselves cannot be objective about what is or is not risky about our own design (inherently biased). There must be enough information in the protocol for someone not directly involved to be able to assess risks/benefits and that data will be secure. Protection is particularly important if a person in a power position is asking someone to participate in research—do not want an appearance of coercion/bias. Role of IRB is to not only protect rights/welfare of participants but also to protect the University (could lose federal funding; reputation; lawsuits). Protects the researcher so that they are not accused of wrongdoing and avoids lawsuits. See attached handout for more details on this topic.

II. **Federal definition of “normal educational practice”** that establishes the type of review for a protocol and establishes the types of protections one must implement to protect against perception of bias/coercion.

Three types of review by IRB:

- **Exempt:** If it is truly normal educational practice, it is exempt from committee review (IRB chair or formal designee can review if considered low risk).

- **Expedited review:** if there is minimal risk gets reviewed by IRB chair and 2 reviewers.

- **Full board review:** if there is more than minimal risk then reviewed by entire IRB board.

Normal educational experience (afterschool, regular classrooms, 4-H clubs) and what is a normal practice is research conducted on teaching strategies, classroom management methods, etc. But the type of research that is typically done in the COE requires expedited or full review because COE research typically involves vulnerable populations (kids) and/or FERPA issues. Researchers who would not normally have access to data would need parental permission. The project moves into the minimal risk category (expedited review) if the data is de-identified and is already “FERPA compliant.” Researchers can get a letter from the school system and present it to IRB (which can help move things along) if already FERPA compliant. Questions about sexual orientation, psychological issues, SES, etc., that is beyond “normal learning” requires an expedited or full review. Questions that go beyond what is typically asked in a classroom cannot be exempt
from review. Studies that create more than minimal risk such as deception moves the project into “not normal educational practice” category, which means expedited or full review.

Note: IRB policies are being revised at the federal level. New restrictions are coming for biomedical research but may see some less constrained policies coming from “beyond normal education” as long as some mechanism is in place to protect participants --- particularly if they are not vulnerable populations. So SoTL research conducted on university students (over the age of 18) may be exempt at some point. See attached handout for more details on this topic.

III. Strategies for designing research to lessen bias/risk to participants: Two areas of problems: (1) Consent or assent forms – language cannot be suggestive of coercion (e.g. wouldn’t you want to help this graduate student get their degree?). (2) Issues of bias – there are often problems in how researchers analyze their data so that they know their students’ responses to survey (for example) before they determine grades. Don’t want their responses to have any influence (intended or unintended) over grades. Good strategy is to wait until after grades are in and THEN look at survey results for the study. Particular problems are when students are asked to judge or review their teacher’s teaching abilities and/or course content (lines of questions such as this are also considered beyond what is considered normal educational practice).

IV. Tips for what needs to be in protocol: The purpose of this literature review section is to educate IRB members to provide them the context for the study and to demonstrate that there is evidence/precedence for the method. They need to know if instruments used in the study are standard practice for this area of research. The more details provided in the protocol, the easier it is for reviewers to determine risks versus benefits to participants. It is rare for someone to get approved without revisions – so plan on revising the protocol (assume that in your project timeline). See handout for more details.

Common roadblocks for researchers:

- Review of literature not complete (Needs to be about 1-2 paragraphs)
- Citations absent
- Procedures are vague and it is hard to know what exactly is going to happen and when (timeline unclear)
- Benefits/risks are not explicitly addressed. Note: there’s always some kind of risk (mental fatigue, etc.). Add something about how the benefits outweigh the risks.
- Lack of consistency between narrative and informed consent (in terms of procedures).
- Be sure to provide all the information asked for by the IRB! Reviewers must comment on the protocols based on what information is supposed to be provided. That’s why they ask for validity/reliability data for instruments.

V. Informed consents: For parental consent and minor assent forms use the guidelines on the ORSSP website. But do not use the headings in the exact order/ language as in the guidelines (e.g., if not doing medical research don’t need to include HIPPA). The informed consent checklist on the IRB/ORSSP website is very useful as well and highly recommended for graduate students. Consent for normal educational practices is that parents need to consent to allow
you to collect the data (mistake is to ask permission from parents for students to participate which is not necessary if its normal educational practice). What is optional/voluntary needs to be outlined in the consent form.

Need to include in your description on the consent form: what is the plan for students who do not give assent or didn’t get consent from parents. What will they do during the time that research is being conducted?

Small group sessions typically done in programs such as in counseling and school psychology need full board review. Need to clarify what professionals will be present, and indicate their credentials, and what will be done of someone does experience emotional distress. If a graduate student has to go to the full board, it is highly recommended that their faculty advisor/chair accompanies them.

Suggestion to graduate students: Be sure that advisors and department chairs have time to review protocols. Could cause delays at the IRB review process if not reviewed carefully for errors omissions.

VI. IRB follow-ups: Speaking with Ele Haynes, the staff member who oversees IRB processes, she agreed to remind her graduate assistants to be mindful of how they categorize “suggested” versus “required” comments on the template. But if an individual gets a review that seems to have mistakenly placed a suggestion in the required category they can always write to the IRB to get clarification. Ele Haynes further agreed to take sample minor assent and sample parental consent off the ORSSP website because these samples are more confusing than helpful given they were written for a specific study. This will encourage people to use the guidelines and checklist to develop the consent documents appropriate for their specific project. Finally, we discussed the timeline for initial feedback from reviewers. Exempt projects 1-2 weeks; expedited 2-4 weeks, and full review 60 days. These are “targets” they strive for but typically remind/nudge reviewers to send in their reviews in as little as 5 days. She stated they usually meet the target. As was emphasized by our panelists, expect to revise your protocol and build that in to your project’s timeline. How quickly and thoroughly a researcher responds to reviewers’ comments will determine how quickly the protocol receives final approval.
IRB Categories for research

Exempt from Committee Review (i.e. low risk; reviewed by IRB chair or designee)
Expedited Review (i.e. no more than minimal risk; reviewed by IRB chair and designees)
Full Review (i.e. greater then minimal risk; reviewed by IRB board)

*all require informed consent and adherence to ethical guidelines in the Belmont report/ common rule.

Definition of an Educational Setting

Any setting where one would go in order to have an educational experience. For example, a public or private school, an after-school club or program, a Boy or Girl Scout meeting, or a professional development seminar for school district personnel.

Definition of Normal Educational Practice

According to CFR 45 part 46.101.b (1), “research conducted in established or commonly accepted educational settings, involving normal educational practices...” is exempt. Federal regulations define normal educational practice 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.” In order to qualify for exemption, a protocol must also demonstrate that participants will not be at greater than minimal risk when they participate.

Conflict #1 Vulnerable Populations

Subpart D of CFR 45 part 46, specifically defines children as a vulnerable population so extra protections for minors apply. Many protocols that seek qualification for normal educational practice deal with children, thus require a level of review beyond exempt.

Conflict #2 Family Educational Rights and Privacy Act (FERPA)

FERPA stipulates that researchers who would not normally have reason or permission to access a student’s educational record, may not access that student’s educational record without prior parental permission. Thus, researchers who would like to collect existing data student records require an additional level of review and parental consent.

Note. The researcher may request that the school provide de-identified data from student educational records as long as students cannot be identified or deduced from the data set. In this case, the data are linked and stripped of identifying information by a third party who has normal access to the data (such as a school administrator). Such data sets qualify for exemption under CFR 45 part 46.101.b (4).

Conflict #3 and Protection of Pupil Rights Amendment (PPRA)

PPRA affords parents certain rights regarding conduct of surveys, analysis, or evaluations, requiring parental notification, permission, and the opportunity to opt out when the topics include personal information about political beliefs, psychological problems, sexual behaviors or attitudes, illegal, anti-social, self-incriminating or demeaning behavior, religious practices, and information about personal relationships.

What is often Considered “Normal”?

- Test development
- Experimentation with instructional methods
- Evaluation of classroom or school activities which may include pre and post testing, surveys, interviews or observations.
- Collecting affective data, specifically attitudes toward learning.

**What is Often Considered “Not Normal”?**
- Interviews, observations, and surveys where the questions and subject matter goes beyond the scope of the educational activity being studied.
- Collecting privileged information such as socio-economic status, sexual information, abuse, etc.
- Educational activities involving procedures that are rarely used and are not considered “best practice” in the field.
- Studies that may involve normal educational practice, but are greater than minimal risk to the students.
- Studies that involve normal practice but take time and resources in a abnormal ways (e.g. lots of test items)

**As Part of a Recent Notice of Proposed Rule Making (NPRM):**

There is increasing desire to better calibrate the level of review to the level of risk involved in the research. A new process would allow studies to be determined to be exempt without requiring any administrative or IRB review (i.e. via some type of online tool) as long as proper procedures are followed.

“Research involving educational tests, surveys, interviews or observations of public behavior when sensitive information may be collected, provided that data security and information privacy protections policies are followed”

This will probably not side step the protections via CFR, FERPA, and PPRA to families and children

**Sources**


1. **The primary purpose of the IRB is to protect the rights and welfare of human subjects**
   - We must protect all human subjects, if there is any federally supported research at the institute.
     - Without the review process, all research monies are lost.

   **How** (Below must be considered by the researcher, but evaluated by the IRB)

   The IRB safeguards individuals involved in research by ensuring that:

   - Risks have been considered and minimized
   - Potential for benefit outweighs the risks
   - Research-volunteers are provided with substantial information about the study and volunteer only after being provided with legally effective informed consent (informed) -
     - You must make a good faith effort to disclose enough information so that they can make an informed decision.
       - You need to describe the nature, scope, and goals of the research
       - Expected duration
       - Any benefits that can be reasonable expected
       - Any foreseeable risks or discomfort
       - All private or identifying information will be handled with confidentiality
   - Competent
     - Legally competent – all adults (unless they have been judged otherwise)
     - Under 18 (not competent) unless emancipated by a judge
   - Voluntary
     - Obtained in the absence of coercion, duress, misrepresentation, or undue inducement
   - Research is conducted in an ethical manner and in compliance with established standards.

2. **Protect the University**
   - From loss of federally supported research grants
     - Without the review process, all federally supported research monies are lost.
   - Protect from lawsuits
   - Protect reputation

3. **Protect the Researcher**
   - From making an error that could potentially put research subjects at risk
   - Protect from lawsuits
Tips Regarding IRB Application Process

Provide all information requested by prompts on proposal narrative.

Include a brief review of literature in support of study and references for any citations.

Avoid vagueness when describing research procedures; methodological details are needed.

Provide sufficient details regarding benefits and risks of proposed research.

Ensure consistency between information provided in proposal narrative, informed consent document(s), and any other appendices.

Use Informed Consent Sample and Informed Consent Checklist (forms on IRB website) to guide development of informed consent documents.

Use language in informed consent documents that is appropriate for participants; avoid use of academic/research terminology.

Describe plan for assisting participants if any possibility exists for negative consequences as a result of research procedures. [If student in Counseling or School Psychology, note in application that research will be supervised by certified professional.]

Be clear on whether you are promising anonymity or confidentiality to participants.

Make sure parents/guardians understand what is being asked of their student; differentiate between what is required of the students as part of class vs. what is optional/voluntary.

Have a plan for students whose parents do not grant consent or for students who do not assent to participate and state this in procedures.

Include all requested appendices including informed consent documents, recruitment materials, data collection instruments, letter of institutional cooperation, and CITI training certificates (both student and advisor for student research).

Proofread IRB application.

Provide sufficient time for research advisor or department chair to review application.

Seek assistance from a COE IRB member prior to submission if you have questions regarding IRB requirements.

Complete class IRB application for student projects if findings will not be disseminated outside of class.

Direct concerns regarding IRB review to the IRB office.