Reviewer Checklist

REVIEW OF EXEMPT RESEARCH

I. The proposal is **Exempt** from IRB review if all aspects of it fall within one or more of the following categories:

A. *In an educational setting, the research or evaluation concerns **normal educational practices** and does not impact the **student research participant's** opportunity to learn required educational content or impact the assessment of educators who provide instruction.*

B. *For research **not** involving vulnerable subjects or sensitive topics – the research involves **benign behavioral interventions***, or the researcher **observes** public behavior, conducts **interviews** or **surveys**, or uses **educational tests,** and either:*

1. subjects cannot be identified directly or statistically, or
2. when subjects can be identified, a Limited IRB Review approves the plan for the privacy and confidentiality of the data, or
3. the data could not harm subjects if they were made public, nor, if subjects give information about others, inadvertent disclosure would not be likely to harm others, or
4. the subject prospectively authorizes deception, if present, i.e. subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

C. *The data, documents, records, or specimens already exist, **and** either:*

1. The subjects cannot be identified in the research data or statistically, and no one can track the subjects' identities, and the researcher does not plan to have contact with the subjects or re-identify the data, or
2. The sources of data are publicly available, or
3. The research is regulated under HIPAA.

REVIEW OF NON-EXEMPT RESEARCH

II. For **Expedited** (i.e., subcommittee) and **Full Board** review, the criteria for eventual approval are the same, but certain categories of proposals

A. *Cannot be expedited:*

1. Research involves more than minimal risk;
2. Subjects can be identified.

B. *May or may not be appropriately expedited:*

1. Research with subjects vulnerable to coercion/undue influence**;
2. Research on sensitive topics***.

Recommend shifting to full board review if you think research raises issues of concern or interest to the entire IRB.

ONLY THE FULL BOARD MAY DISAPPROVE A PROTOCOL. CHECK "**FULL BOARD REVIEW**" IF YOU BELIEVE THE PROTOCOL SHOULD NOT BE APPROVED.

III. Criteria for **Approval** (from 45 CFR 46.111)

A. *Risks to subjects are minimized.*
Risks refer to magnitude of harm and probability of incurring harm. "Minimal risk" is keyed to experiences of a non-vulnerable person in ordinary daily life or in routine medical, dental, psychological examinations. [Scrutinize risks especially when the topics are "sensitive."]

B. *Risks to subjects are reasonable in relation to benefits.*
If more than minimal risks, does **scientific merit** outweigh risk? Are **benefits maximized**? Are **risks minimized**? [Scrutinize especially when populations are vulnerable to coercion/undue influence.]

C. *Selection of subjects is equitable.*
[Scrutinize especially when populations are vulnerable to coercion/undue influence.]

D. *Informed consent is properly sought.*
1. Key information essential to decision-making receives priority in informed consent by:
   I. Being presented first in the consent discussion;
   II. Appearing at the beginning of the consent document.
2. An explanation of the purpose of the research, duration and procedures to be used is provided at a language level the subject will comprehend.
3. Major deception (e.g.) intentionally misleading subjects about their status, giving false information about the researcher(s) or the project), and minor deception (e.g. withholding some information about the purpose of the study to avoid biasing the results) **should be justified** and plans for debriefing subjects should be outlined. If possible, consent forms should warn subjects that some deception is involved. [Scrutinize especially when populations are populations are vulnerable to coercion/undue influence; parental permission is required for children, child's assent is needed depending on the age and type of research.]

E. *Informed consent is properly documented.*
[If waiver from WRITTEN consent is requested, decide whether ORAL consent should be witnessed.]

F. *Subjects are monitored during data collection to ensure their safety.*

G. *Subject's privacy is **adequately** protected and data is maintained confidentially (when appropriate).*

H. *Populations vulnerable to coercion or undue influence are adequately protected from coercion or undue influence (e.g. from excessive compensation or inequitable relationship between research and subject.)*
[Additional safeguards have been included in the study to protect the rights and welfare of these subjects.]

*__Benign behavioral interventions__ are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

**__Vulnerable subjects__ In the revised rule, provisions for vulnerable subjects focus on *vulnerability to coercion and undue influence*. The list of categories of subjects that are vulnerable in this way comprises children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons.

***__Sensitive topics__ include: sexual orientation, sexually-transmitted diseases, incest, rape or date-rape, sexual harassment, molestation, race relations, use of licit or illicit drugs, eating disorders, abortion, contraception or pregnancy, the subjects' own mental health (suicide, depression, compulsive behaviors), religion, illegal conduct, stressful experiences.